Hospital discharge planning and interface liaison for elderly care patients

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HOSPITAL DISCHARGE PLANNING AND INTERFACE LIAISON FOR ELDERLY CARE PATIENTS

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ABSTRACT

This thesis examines the influence of medication counseling and the improve communication with General Practitioners (GPs) and community pharmacists (CPs) regarding discharge medication. The project addresses in particular the way in which patient medication adherence and knowledge can be improved by such counselling. By following-up patients post discharge any medication-related problems (MRPs) could potentially be identified and resolved by a visiting hospital based pharmacist particularly those problems related to interface issues. This project also attempts to describe a scheme of quantifying such MRPs.

122 elderly patients to be discharged from a London teaching hospital with one or more regularly prescribed medicines were randomly allocated to two groups. The intervention group received intensive medication counselling supported with written information and details sent to the GPs and CPs while the control group received the usual discharging procedures. Patients were initially assessed using the Nottingham health profile and a patient's knowledge questionnaire. All patients were visited at home two and six weeks post discharge. The intervention group patients only were counselled and any MRPs identified resolved. Patients' knowledge, compliance, quality of life and satisfaction with information were assessed during these visits. MRPs were also identified and categorized using two different systems.

Counselled patients showed better knowledge and adherence in comparison to the control group, but no further improvement was observed after the first home visit. While patients of the intervention group showed higher levels of satisfaction with the information provided. The intervention provided did show statistically better score for the NHP at two weeks, but there was little difference at six weeks due to a general improvement in both groups.

Overall, the number of medication-related problems rated at two and six weeks were generally lower in the intervention group, although there were few instances of contraindications and drug interactions. Regarding the severity of problems, the intervention group demonstrated a reduction in moderate problems rather than the minor or severe MRPs between the first and second home visit. There were significantly fewer potential MRPs in the intervention group caused through a poor knowledge of health and medicine-related issues and this may be a reflection of the counselling process. The intervention group showed higher incidences of ADRs which may be due to improvement in patient knowledge regarding ADRs.

25% of the patients in the control group had identifiable interface problems at two weeks interval after discharge where 12% of the intervention group had such problems. On the second visit only 10% of intervention patients and 12% of control patients had these problems. This may indicate that such problems are resolved post discharge but may be prevented by good communication with the GPs and structured counselling pre-discharge. Prescribers were contacted concerning MRPs for 34% of the intervention group patients after the first home visit and for only 10% for the second home visit.

It is concluded that discharge medication counseling together with the relevant information sent to the GPs and CPs can reduce MRPs and improve patients' adherence to and knowledge about medication. Further domiciliary visits at two weeks can also further reduce MRPs, but has little benefits concerning adherence and knowledge of medication. The process can be conducted with relatively junior staff.

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Abbreviations

ACEI: Angiotensin Converting Enzyme Inhibitor
ADRs: Adverse Drug Reactions
A&E: Accident and Emergency
BMQ: the Beliefs about Medicines Questionnaire
BNF: British National Formulary
CPs: Community Pharmacists
DIs: Drug Interactions
DHC: Dihydrocodeine
DoH: Department of Health
DRPs: Drug-Related Problems
GP: General Practitioner
HCPs: Health Care Professionals
HRQL: Health Related Quality of Life
LSL: Lambeth, Southwark and Lewisham
LSIA: Life Satisfaction Index
LSLHA: Lambeth, Southwark, Lewisham Health Authority
MAI: Medication Appropriateness Index
MARS: the Medication Adherence Report Scale
MRPs: Medication-Related Problems
MSQ: Mental Status Questionnaire
NHP: Nottingham Health Profile
NHS: National Health Service
NSAIDs: Nonsteroidal Anti-inflammatory Drugs
NSF: National Service Framework
OTC: Over the Counter
PCGs: Primary Care Groups
PCNE: The Pharmaceutical Care Network Europe
PCTs: Primary Care Trusts
PMR: Patient Medication Record
POM: Prescription Only Medicines
QoL: Quality of Life
SE: Side Effects
SES: Southampton Self-esteem Scale
SF-36: Short Form 36
SIMS: Satisfaction with Information about Medicines Scale
SIP: Sickness Impact Profile
SPSS: Statistical Package for the Social Sciences
TTO: To Take Out

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Preface

This thesis is divided into seven chapters. Chapter One is the introduction to the thesis and is composed of the background and the literature review. Chapters Two, Three and Four present the methods used to achieve the thesis aims, the fieldwork and the pilot study and the main study respectively. Chapter Five presents the results obtained from the main study. The last chapter interprets and discusses the results.

Chapter One- Background and Literature Review

The introduction to this thesis describes drugs in the elderly and their behaviour towards their medication. This chapter also discusses the importance of pharmaceutical care and the effect of medication review on improving patient's compliance and reducing the effect of different medication-related problems. A particular section is devoted to examining other similar studies to that concerned by this thesis. This chapter concludes by explaining the rationale of this thesis.

Chapter Two- Methods

The various methods employed to achieve the objectives are presented in this chapter. These methods vary from questionnaires (mental status questionnaires, patient's knowledge questionnaire, quality of life questionnaires and satisfaction with information instruments) to medication-related problem classification systems.

Chapter Three-Preliminary Fieldwork and Pilot study

The preliminary fieldwork in this chapter describes the demographics in St.Thomas' hospital where the first part of the study was conducted. It also describes a scoping study to explore the opinions of some healthcare professionals concerning the discharge procedures and the problems that may be faced during this process. The second section in this chapter describes the training for using the checklist system and for conducting structured medication counselling prior to hospital discharge. The last section describes pilot work to examine the use of the various tools and instruments used in the main study.

Chapter Four- Main Study

The main study describes the following: recruitment procedure; patient group allocation; conducting structured discharge counselling and following the patients up after leaving the hospital through domiciliary visits to review their medication and to identify any medication-related problems.

Chapter Five-Results

This chapter outlines the characteristics of recruited patients and the effect of the hospital discharge counselling and information transfer during domiciliary visits on various patients outcomes. The last two sections quantitatively highlight the different identified medication-related problems and classify the problems according to two different systems. Also, described any interventions that occurred during the study concerning patients medication and the rate of hospital readmission during the period of this study.

Chapter Six-Discussion, limitations and conclusion

This chapter discusses the results in the context of the literature published in the field.

INTRODUCTION

INTRODUCTION

Older people have the right to be able to enjoy good health and remain independent for as long as possible. As people get older, remaining independent often relies greatly on services being effective enough to provide adequate support (National Service Framework for Older People DoH, 2001).

Older people are considered the greatest consumers of health and social care services but sometimes services have not properly addressed their needs. In 1998/1999 the NHS spent about £4 billion which represented 40% of its budget on elderly over the age of 65 and in the same year social services spent nearly £5.2 billion (50%) on the over 65s. Older people are in greater need for health and social services than the young, so the majority of health and social care resources are directed to address this need (National Service Framework for Older People DoH, 2001).

Older people experience a high incidence of medication errors with evidence suggesting that they do not take their medication as prescribed (Col *et al.,* 1990). This may often result in poor disease control, drug wastage and can also contribute to hospital admissions. Compliance with a drug regimen is therefore a major issue among older people, particularly for those who live alone, are confused, or suffer from poor vision, impaired manual dexterity or a poor memory (Griffith, 1990). The benefits of medication education and self-medication programmes have been explored in various studies (Ascione and Shimp 1984 and Esposito, 1995). Many of these studies have adopted a consistent approach to patient education by which all patients receive the same quantity and quality of information whilst only few have tailored education programmes to acknowledge the needs and motivations for different patients (Ryan and Chambers, 2000).

Drug-induced disease in the elderly is under-recognized, and poor drug compliance plays a substantial role. It has been reported that about 5% of hospital admissions are due to drug-induced diseases and that a percentage of these admissions are related to the improper use of medication by patients. Many older people live with long-term illness and if they have been

provided with appropriate information, they may be able to better participate in managing their own conditions. Furthermore, it is also important to meet the general information needs of carers (National Service Framework for older people DoH, 2001).

It has been recognized in Herrier's review (1995) that a patient's non-adherence to prescribed therapy is a major contributor to poor therapeutic outcomes in both short and long-term illnesses. An estimated 10% of hospital admissions in United State of America is due to non-compliance and that around 125,000 deaths annually in patients with cardiovascular diseases may be related to adherence issues. More than 100 billion dollars are spent annually to cover the economic costs of hospitalisation because of non-adherence, outpatient visits, emergency room visits and admissions to nursing home.

The likelihood of adverse drug reactions is compounded in the elderly by mental impairment, multiple diseases, polypharmacy, and physiological changes (*e.g.*, decreased renal and hepatic functions). Proper understanding and good compliance regarding medication is a key element to avoiding medication-related problems. Patient's compliance is affected by many factors, including patients' memory, knowledge of their medications, expectations and satisfaction, and the relationship between doctor and patient. Compliance is also affected by impairment of eyesight and manual dexterity which can make it difficult for medication self-administration especially for medicines in child-resistant containers. While it has been suggested that the majority of elderly patients can accurately repeat dosage instructions, up to 75% make errors in dosage administration, 25% of which are potentially serious (Blenkiron, 1996).

It has been argued for many years that drug-induced errors could be reduced even in the highly confused patients if clinical pharmacist managed to interview and counsel elderly patients for about 15 minutes before discharge, to make sure that they understand and remember their drug regimes (MacDonald *et al.*, 1977). Although pharmacists may answer patients' queries as they arise on ward visits and nurses may advise patients on an informal basis, there is often no formal method concerning delivery of this information. One aim of this study is to attempt to construct an intervention to enhance the quality and quantity of

information patients receive prior to their hospital discharge. A further aim of the study is to enhance compliance to prescribed medication post-discharge.

Interface issues are the other major factors concerning appropriate medication discharge planning. Generally speaking, there is usually formal communication between hospital and community pharmacists about individual patients to ensure that the correct information is being transferred to the community services and these are appropriately delivered (Smith *et al.*, 1997).

A potential scenario is that confusion arises regarding intention of changes to medication taken prior to discharge and the failure to understand these intentions by either the patient or general practitioner (GP). Such problems may cause therapeutic failures, increased incidence of medication-related problems and may end with hospital readmission. A study by Cochrane *et al.* (1992a) highlighted the discrepancies in treatment that may occur post discharge and in many cases these changes could not be attributed to a conscious clinical decision. Closer communications between the different healthcare professionals between the primary and the secondary care interface are therefore required to ensure this smooth continuity.

The role of the community pharmacist in the United Kingdom has expanded from just dispensing related activity to treating minor illness, supervising medication in the community and advising general practitioners about cost-effective prescribing. Domiciliary pharmaceutical service can be an important part of this new role especially for patients who are unable to visit a pharmacy. Domiciliary pharmacy visits also provide the opportunity for the pharmacist to understand the patient's medicine-taking behaviour and to obtain an insight into the support system available to the patient (Begley *et al.*, 1997).

It is the purpose of the present study to investigate a discharge and follow-up programme conducted through hospital pharmacy services. This study will also contribute to developing and assessing methods of overcoming interface issues concerning discharge medication. Outcomes will be assessed in terms of patient quality of life, compliance, patient knowledge and patient satisfaction with the service they received. The other major outcome to be

assessed in this study is identifying and reducing the incidence of potential medication related problems that patients may be exposed to after their hospital discharge.

This thesis comprises of seven chapters. The first chapter will include the background and literature review. Chapter two will include the scope of work, different aims, objectives and hypotheses. The third chapter will describe the different methods employed, questionnaires and instruments used to conduct this project. Chapter four and five will include the pilot study and the plan of the project including patient recruitment, hospital discharge planning and domiciliary visits given to the patients after their hospital discharge. The last two chapters will consist of the results, discussion, summary and the recommendations for future work.

CHAPTER ONE

BACKGROUND AND LITERATURE REVIEW

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BACKGROUND AND LITERATURE REVIEW

Aspects of different problems in the elderly related to medication compliance, drug knowledge, interface issues and medication-related problems relevant to the present study are reviewed in this section.

1.1 Drugs in the Elderly

Elderly people are those 65 years of age or older, and within this population, those over 75 years of age represent one of the fastest growing categories (Higbee, 2000). The United Kingdom is considered an ageing society; since the early 1930s the number of people aged 65 and over has doubled and today about 20% of the population is over 60 (National Service Framework for Older People DoH, 2001). People aged 65 years and over comprised 10.9% of the United Kingdom population in 1951 (Tinker, 1997). For 2001, estimates showed that 16% of the national population are aged 65 and over, and this is forecast to rise to 21% by 2026 (DoH, 2002), with an increase in the consumption of greater proportion of the NHS services and resources. This is of concern to healthcare professionals since those greater than 75 years of age may suffer the most severe consequences of diseases and drug therapy due to significantly diminished homeostatic reserve (Vestal, 1997) and they are more susceptible to medication-related problems (MRPs) than younger patients (Bellingan and Wiseman, 1996).

People aged 65 years and over, despite representing only 20% of the United Kingdom population, consume a significant amount of healthcare resources (Krska and Jamieson, 2000). About 70-80% of those aged 75 and over are taking prescribed medicines, most are considered as long-term treatment (Blenkiron, 1996). Elderly patients account for approximately 25% of physician visits, about 35% of prescription drug expenditures and 40-45% of over-the-counter (OTC) drug sales annually (Vestal, 1997). Ninety per cent of the elderly in the community take at least one medication with an average of at least four drugs per patient and approximately 67% of elderly take at least one OTC. In addition, problems with concomitant use of herbal medicines should be considered and these problems may be attributed to two factors: little is known about the basic pharmacology of these botanical

agents and there is no standardized manufacturing process to assure safety and efficacy (Vestal, 1997).

As mentioned above, inappropriate prescribing occurs more often in elderly patients and this can result in an inadequate response, side effects and toxicity that can interfere with the therapeutic outcomes. Polypharmacy is almost unavoidable with aging, adverse drug reactions may result in prescribing another medication to treat a side effect which may lead to increasing polypharmacy or stopping of a needed medication where a dose reduction would be the solution. This may stem from failure to recognize the particular needs of the elderly patient and a lack of data regarding the use of particular drugs in the elderly. The elderly are at risk for multiple reasons, which makes it imperative for the health care professional to focus on the elderly with regard to their specific profession (Higbee, 2000).

The majority of the elderly live in their own homes, less than 5% are living in residential homes or institutional care and about 25% are unable to leave their homes without some sort of assistance. Therefore, some may be unable to visit their community pharmacy and the only source for pharmaceutical service is through carers (Begley *et al.*, 1997). Due to several factors; multiple pathology, polypharmacy, altered pharmacokinetics and pharmacodynamics, reduced visual acuity, impaired cognitive function, and physical difficulties, elderly patients are very vulnerable to the effects of medication. This often influences patient adherence to the medication regimen (Begley *et al.*, 1997).

The role of the pharmacist in the healthcare system is expanding from the traditional drug-oriented function to a cognitive oriented function. The concept of pharmaceutical care is being advocated, which enables pharmacists to describe their further evolution as patient-focused health care providers (Hepler and Strand, 1990).

The topic of seamless pharmaceutical care and the factors that influence this concept and drug therapy management in the elderly will be covered in this section.

1.1.1 The National Service Framework for Older People

There is an emphasis on designing services around the needs of the patients so that they have quicker access to high quality health care (Secretary of State for Health, 2000). Much of the care that took place in hospitals is now taking place in primary care and in the patients' own homes. Secondary care now plays a supportive role to the work of primary health care professionals (HCPs) to manage individual requirements.

A range of measures were introduced by the NHS to increase quality and decrease variations in service and one of these measures is the National Service Framework (NSFs) for older people. This particular National Service Framework is the pioneering strategy to ensure high quality and integrated health and social care services for older people. Many major diseases and conditions are more common in older patients. National Service Frameworks (NSFs) were established to improve services through setting national standards to improve quality and tackle existing variations in care. The NSF for older people is the third to be produced after the mental health and the coronary heart diseases and sets standards for the care of older people in all settings across health and social services. In addition, it focuses on those conditions, which are of particular significance for older people, and which have not been addressed elsewhere, *e.g.*, strokes, falls and mental health problems. The NSF for older people is a 10 year programme of action connecting different services to support independence and promote good health, specialised services for key conditions, and culture change so that all older people and their carers are treated with respect, dignity and fairness. It sets out a programme of plans and actions to address the problems and deliver services of higher standards for older people. The plan also proposes more consultants, nurses and therapists working for older people. This framework is the result of extensive consultation with older people, their carers and the professionals involved in the care of elderly people (National Service Framework for Older People DoH, 2001).

The NSF for older people has set certain milestones to be achieved, these milestones relating to medication include:

- Annual medication review for all people over 75 and biannual medication review for those taking four or more medicines.

- All hospitals should have "*one stop dispensing/dispensing for discharge schemes*" and self-administration schemes for medicines for older people should be considered.

- Every primary care group or primary care trust will have schemes in place so that older people get more help from pharmacists in using their medicines

1.1.2 Multiple Diseases in Elderly

There is an increased incidence of chronic disease with age, particularly after the age of 75. Multiple diseases are common in the elderly, with a high proportion having one or more chronic illnesses as compared to young adults (Vestal, 1997).

The most frequently diagnosed diseases in elderly patients are arthritis, heart diseases, hypertension, hearing impairment, orthopedic disabilities, vision impairment and diabetes mellitus. Of these conditions, heart disease, hypertension, diabetes, arthritis, and visual impairment are the most frequently cited causes of disability (Higbee, 2000).

1.1.3 Polypharmacy in Elderly

Polypharmacy is "*the concurrent use of several different medications used by the same individual, which in some cases can lead to medication-related problems*" (Colley and Lucas, 1993). Since the elderly exhibit a higher incidence of illness, then it follows that their medication use will also be consequently higher. The increased drug utilization in long-term care is explained by their increased acuity. Additionally, many common diseases in the elderly require multiple drug therapy in order to properly control and treat the disease *e.g.*, congestive heart failure and diabetes mellitus. Thus, it follows that the elderly will consume a greater number of medicines (Higbee, 2000).

This problem is widely recognized as an international problem, Titley-Lake and Barber (2000) showed in their study the patterns of medication use amongst the elderly where medication reviews were carried out on 50 of the elderly patients of the British Virgin Islands in the Caribbean. The average number of prescribed medications was 4.5 medicines (range 1-10) and about one-third of the patients used more than five medicines. Self-medication was very common among the recruited sample. The vast majority (98%) reported using OTC

preparation with an average of 4.7 products and 76% also used herbal remedies and natural products with an average of 3.3 products/patient. The most commonly prescribed medication for elderly patients were cardiovascular drugs (86%), followed by endocrine drugs (40%) used mainly in the management of diabetes mellitus. Many patients were also prescribed drugs used for nutrition and for blood disorders (28%), musculoskeletal and joint disease (26%) and eye conditions (18%). Vitamins and supplements were the most likely consumed products for OTC self-medication, as reported by 60% of the patients. Treating or preventing the disorders of the gastrointestinal tract was also a major reason for the use of natural products or herbal remedies. A high proportion of patients used these products for a wide range of ailments, including skin, eye and prostate disorders, infections, stress, insomnia, to boost the immunity system and to enhance memory. As this study was performed on a limited population (elderly in the British Virgin Islands) it is difficult to generalize the conclusion; however, it appears that the elderly are harbouring more diseases than younger patients and because of this, polypharmacy is the rule rather than the exception. A similar study was carried out in the UK by Blenkiron (1996) where four medications per patient was the commonest number of drug prescribed among 80 patients aged 75 years and above. The most widely prescribed medications were analgesics, diuretics, antacids, Glyceryl trinitrates, Aspirin, NSAIDs and laxatives. The agreement between the two studies indicates a true international perspective of the problem although in the second study, patients' compliance was also assessed using the self-reported technique which is normally provides overestimated results.

There is good evidence that increasing the complexity of the drug regimen would lead to difficulties with medication utilization and that the incidence of medication errors can rise with as increased number of prescribed items (Eisen *et al.,* 1990). It was found that prescribing more than two medications per day can lead to a three-fold increase in the likelihood of self-reported non-compliance. It has also been found that about one quarter of elderly patients were taking an OTC medication for conditions also being treated with prescribed medication. Generally speaking, the aim of any treatment regimen should be simplification of that regimen and that any single medication is not prescribed more than twice a day (McElnay *et al.,* 1997).

It can be concluded from the above that, polypharmacy is a major risk factor for drug-drug interactions and adverse drug reactions because their incidences increase exponentially with the number of prescription and OTC products being taken. Prescribing simpler regimens with fewer tablets to be taken each day and a small number of different medications may also reduce the patient's risk of non-adherence.

As mentioned before, people aged 65 years and over are major users of medication. The greater the number of medications being consumed the higher the incidence of the adverse drug reactions. This will be discussed in the following section.

1.1.4 Adverse Drug Reactions in Elderly

Adverse drug reactions (ADRs) are defined as an "*undesirable clinical manifestation consequent to and caused by the administration of a particular drug or interacting drugs, excluding overdose, substance abuse and therapeutic failure*". These clinical manifestations may be presented as an abnormal sign, symptom or laboratory test, or a cluster of abnormal signs, symptoms and tests, but (except in a case of asymptomatic high drug concentration in the blood) it does not depend on laboratory test alone (Mannesse *et al.*, 2000).

Elderly patients are at higher risk of adverse drug reactions (ADRs) as a consequence of age-related physiological changes. It was reported that the rate at which the elderly exhibit ADRs was two to three times higher than those exhibited by younger adults (Higbee, 2000). ADRs have been estimated to be responsible for 10-13% of all hospital admissions of elderly patients (Nathan *et al.*, 1999). In an observational cross-sectional study carried out by Mannesse *et al.* (2000) in five wards in the Netherlands, it was found that 12% of patients aged 70 and over were hospitalized because of ADRs. Risk factors for these medication-related problems are falls before admission, the presence of gastrointestinal bleeding or hematurea and use of three or more medications. Hospital admission due to fall may be the manifestation of severe ADRs in the older patients. It can be concluded from this study that medication-related hospital admission of elderly patients is an important problem and responsible for about 17% of the hospital admissions.

Col *et al.* (1990) interviewed 315 elderly patients (average age 76.6 years) who were admitted to an acute care hospital. Twenty eight percent of the admissions (89/315) were due to medication-related problems with 16.8% related to adverse drug reactions. Fifty-three patients (16.8% of all admissions) suffered 55 adverse drug reactions. Thirty were assessed as side effects, 15 were toxic reactions, 1 was an allergic reaction, 2 were idiosyncratic and 7 were unclassified reactions. The drugs most commonly implicated in hospitalization due to adverse drug reactions were Warfarin and Prednisolone. It was also found that the greater the number of different medications prescribed, the greater the rate of admissions related to adverse drug reactions. In the same study by it was found that, adverse drug reactions were 8.8 times more prevalent among those using two or more pharmacies than among those using a single pharmacy. Analysis of the results in this study found the following variables to be associated with hospitalization due to adverse drug reaction: the number of the medications prescribed; whether the patient suffered from any fall, and if the patient had received any follow-up on domiciliary visit. Also patients using two or more pharmacies had a slightly higher prevalence of adverse drug reactions than those who used only one (15.8% *vs.* 12.1%).

Specific drug classes would certainly have a greater tendency to cause ADRs in the elderly, which may lead them to stop taking these medications. For example, psychotropic medications may cause sleeping disturbances and constipation may be caused as a consequence of taking antimuscarinic drugs. Other problems encountered are the therapeutic effects which may lead to an unacceptable alteration in patient's lifestyle. The well-recognized example for this is the problem imposed by diuretics, where the patient may omit drug dose on the days that he/she is away from home. Stewart and Caranasos (1989) pointed out in their review that, generally, compliance is likely to be reduced if medication requires some behavioural change in a patient.

Definition, identification and classification of drug-related problems will be discussed in more details in section 1.3 in this review.

As mentioned previously, the aging process may result into physiological changes in both renal and liver function which in turn may lead to alterations in body composition and

alterations in drug pharmacodynamics and pharmacokinetics as well as impairment of the homeostatic mechanisms that regulate blood pressure, body temperature and intravascular volume which often contribute significantly to the increase of the incidences of ADRs in the elderly (Vestal, 1997). For example, Digoxin has a decreased volume of distribution and a decreased renal excretion with age. Therefore, elderly patients are at risk of overdose when prescribed the standard doses that are normally prescribed for younger adults. It is such situations that may lead health care professionals to inappropriately believe that the elderly are more "sensitive" to drugs (Higbee, 2000).

1.2 Pharmaceutical care

The main purpose of this study is to use interventions that might improve the ***pharmaceutical care*** for elderly patients up to two months after their discharge from hospital. This section examines pharmaceutical care, particularly as it relates to the elderly.

1.2.1 Pharmaceutical Care and Medicines Management

One definition of seamless care which appears to reflect most closely the aspirations of those who work for the National Health Service is that suggested by Jackson *et al.* (1993): *"The process by which patients are moved across the boundary between primary and secondary health care sectors with assurance that all their health care requirements, including information, can be communicated and maintained in a safe, timely, efficient and user friendly way and without experiencing any gap in the standard of their health management".*

The term "*pharmaceutical care*" was initially developed to describe the pharmacists' potential role as patient-focused healthcare providers and direct their services from a product-oriented to service-oriented provision. The community based pharmacist will move into a clinically focused role, more which involves patients, doctors and other healthcare professionals, where appropriate (Anonymous, 1996).

In 1990, Hepler and Strand provided another definition of pharmaceutical care as:"*The responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life*". They defined these outcomes as:

- Curing diseases.
- Eliminating or reducing patient's symptoms.
- Stopping or slowing the disease process.
- Preventing a disease or symptom.

Pharmaceutical care involves three major functions on behalf of the patient (Hepler and Strand 1990):

- Identifying potential and actual medication-related problems.
- Solving actual medication-related problems.

- Preventing potential medication-related problems.

The broad elements involved in pharmaceutical care process as reported by Jackson *et al.* (1993) are:

- Identification of patient's need for continuing professional input.
- Collation of patients' details relevant to their requirements.
- Presentation of information in a format relevant to each health professional/ carer likely to be involved with the patient.
- Professional interaction with the patient in his/her new environment.
- Recording of all relevant details in the most appropriate database.
- Follow-up and monitoring of services those are currently being provided and may be required in the future.
- Audit of cost–effectiveness of professional input.

Implementation of a pharmaceutical care plan requires pharmacists to interact with both patients and healthcare professionals (Krska and Jamieson, 2000). Pharmaceutical care involves the process by which a pharmacist can meet a patient's drug therapy requirements and those of other healthcare professionals in designing, implementing and monitoring a therapeutic plan that will produce specific outcomes for the patient. In 1992, a policy statement on the pharmaceutical aspects of community care recommended that, prior to the discharge of patients with identified needs; hospital pharmacists should establish links with their community colleagues (Anon, 1992).

When providing pharmaceutical care, pharmacists can learn more about their patients; their medicines; the way they see them and their beliefs about their health and medications. In addition to spending time with the patients, pharmacists need to ensure patients understand how to use their medications as well as making interventions to improve the outcome of the medication therapy. The aim for pharmacists in providing pharmaceutical care is "*to identify, resolve and prevent drug therapy problems before they happen and to solve problems that have already happened*" (Currie, 2003).

An important part of the patients' healthcare requirements is the management of their medicines; this role is incorporated in the pharmacist's range of professional responsibilities, embodied in the term of "*pharmaceutical care*". Hepler and Strand (1990) explained the term "*Pharmaceutical care*" as directing pharmaceutical input to the needs of the individual patient with the aim of improving the patient's quality of life. Thus a patient moving from a primary care setting into secondary care, or vice versa, should not be at a disadvantage in terms of the continuality, consistency or quality of the pharmaceutical care they receive. At present, pharmaceutical care is practised in hospital through available clinical pharmacy services, but these must be transferred to be practised in the community to prevent a waste of resources because of either unnecessary visits to the GP or readmission to hospital (Smith *et al.*, 1997). Widely, the medicines management philosophy is not been practised in the community setting at the present time.

"Medicine management" is a term that the Department of Health in UK has recently introduced, although in many situations this is very similar to the concept of the pharmaceutical care. One possible reason for introducing this term might be to embrace any health professional, whereas pharmaceutical care is often seen as pharmacist-related activity. Another possible reason may be political, where the concept of a new "care" based service might be seen for demand additional resources. It is certainly seen to embrace practice in the community

A full definition is given on the managing medicines website as: *"In full agreement with the doctors and patients concerned, pharmacists will be able to take the initiative in managing the medication of certain patients, dispensing repeat medication and varying prescriptions if necessary, all in accordance with pharmaceutical care plans. In the process, pharmacists will talk to patients regularly about their medicines and the progress of their condition (in pharmacies or patients' homes), monitoring use of medication, checking for side effects and interactions and referring back to doctors when needed. Pharmacists will ensure that patients have consistent packages of pharmaceutical care and that, in transfers between home and hospital (and within hospital) and is transferred uninterruptedly and managed smoothly. There will be joint consultations between doctors and pharmacists, appropriate*

records will be fully shared and, in some cases, particular hospital or community pharmacists will specialize in complicated conditions and concentrate on helping those patients in greatest need" (managing medicines website, 2004).

Tweedi and Jones (2001) offered another definition of medicine management "*the systematic provision of medicines therapy through the partnership of effort between patients and professionals to deliver best patient outcome at minimized cost*". This concept is built-up from four key-elements: **c**linical excellence, **c**ollaboration of participants, **c**ost control and **c**oncordance.

The overall goals of the Department of Health's Medicines Management Services Programme are (managing medicines website, 2004):

- Identifying and addressing unmet pharmaceutical need
- Helping patients to get the best from their medicines and thereby delivering real improvements in health
- Developing innovative medicines management approaches that have the patients' needs uppermost whilst also improving service efficiency and reducing waste
- Providing convenient access to a range of medicines management services in different environments through multidisciplinary working which builds on the strengths of pharmacists

In reality, pharmaceutical care is considered as a type of medicines management. Barber (2001) has compared the two concepts of pharmaceutical care and medication management and concluded that both were created from limited point of view, that of the care of the patient in the case of pharmaceutical care, and that of the healthcare provider in the case of medicines management. It may be that the Department of Health prefers the term "medicines management" because of the doctors' sensitivity. Medicines management allows for a variety of practice and process to fall within it and involves all the healthcare professionals and patients in the proper use of the medicines (Simpson, 2001). By using this term, the doctor becomes the director of an expanded primary healthcare team (Tweedie and Jones, 2001).

As the majority of the elderly people are taking one or more medicines, medicine management is an important requirement in each of the NSF standards as well as dealing with relevant medicines issues within the NSF itself. That is why this issue therefore forms part of the NSF for Older People (National Service Framework for Older People DoH, 2001).

1.2.2 Medication Review and Domiciliary Services

The follow-up of a patient's drug therapy is an important element in the practice of pharmaceutical care. Clinical medication review can be defined as "*the process where a health professional reviews the patient, the illness and the drug treatment during a consultation. It involves evaluating the therapeutic efficacy of each drug, unmet therapeutic needs and the progress of the conditions being treated. Other issues, such as compliance, actual and potential adverse effects, interactions and the patient's understanding of the condition and its treatment are considered where appropriate*" (Lowe *et al.*, 2000a). This process can be performed by visiting a residential facility such as nursing homes or in the patients' own homes. Sometimes this may take the form of the "*brown bag review*" where the patients are asked to bring into the pharmacy all their medications for review. This concept was developed in the USA in 1982, consisting of a structured method of review of patients' medication conducted by pharmacists. It involves inviting patients to bring along all the medication they have at home (both prescribed and bought over the counter, any out of date products, or any medicines no longer used, and any reserve supplies) to the pharmacy or any other convenient setting to be reviewed by a pharmacist (Nathan *et al.*, 1999). The brown bag concept aims to provide the patients with better understanding of all of their medicines and helps to identify and fill gaps in patients' knowledge about the purpose and the use of their medication. Another advantage of this scheme is to increase patients' confidence in their medicines. The extended contact between pharmacist and patients during the medication review can facilitate a better personal relationship and provide an opportunity for in-depth discussion rather than simply reviewing information from the point of the dispensing of individual medicines (Nathan *et al.*, 2000).

Recently, the National Service Framework for Older People (2001) has proposed that "*all elderly patients on repeat medications should be reviewed annually and those on more than*

four medicines should be reviewed twice a year". Because of the pressing priorities of GPs, it has been suggested that pharmacists might be the best candidates to perform medicines reviews of patients on repeat prescriptions (Petty *et al.*, 2002).

Petty *et al.* (2002) described the nature of the interventions made by pharmacists carrying out clinical medication reviews in general practices for elderly patients on more than one medication and responsible for administering their medication. Permission was obtained to make alterations to the patients' treatments in specified circumstances without the need to refer the patient to the GP but patients were referred to the nurses or GPs if necessary. Six hundred and eight elderly patients were recruited, 590 patients were interviewed, 258 (44%) received recommendations for changes in their medication which included consultations (29%), doctor referrals (5%), and nurse referrals (4%). Medication reviews were performed at the GP surgeries which would make the review more effective as the investigator had direct contact with both the patients' notes and the responsible GPs. It was concluded from this study that pharmacists can implement most of the interventions without the need to refer the patient to either a doctor or nurse.

Another form of the medication review is the general practice medication consultation between the patients and pharmacist. In a study by Lowe *et al.* (2000b), 161 elderly patients (77 in the intervention group) taking at least three medicines were assessed by a clinical pharmacist. A medication review was performed in the community to assess their understanding of their medication and compliance using a structured questionnaire. Intervention patients received medication review which aimed to reduce the dosage frequencies, stopping unnecessary medications and any modification of the medication containers. The medicine regimen of the intervention group was changed in approximately half the patients. Any changes in regimens were discussed with the patient. All patients were reassessed after a month. On reassessment, the average score for compliance for the intervention group was 91.3% compared to 79.5% for the control group. Eighty-eight percent of the intervention group correctly recalled the purpose of the medication they were taking compared to 70% of the control group. The researcher concluded from these results that

"Medication review and patient's education in the community can significantly improve patient's knowledge of and compliance with medication in the short- term".

The third form of the medication review is the one represented by domiciliary visits. Domiciliary service should be one of the priorities of "care in the community" and a follow-up visit at home after discharge from the hospital would help in this process. The need for domiciliary visits was recognized by the Department of Health and the Pharmaceutical Profession Joint Working Party (1992), it was reported that "*arrangements should be introduced to provide domiciliary pharmaceutical services for patients who are unable to use the pharmacy in person*". Medication-related problems, which may include appropriateness of the treatment, interactions, ADRs and adherence could be identified and acted on. Also, any medication problems experienced in hospital could be monitored and followed-up in the community. In this way, pharmaceutical care would be continued and the number of medication-related readmissions to hospital due to non-compliance perhaps reduced (Cook, 1995).

In a study carried out by Schneider and Barber (1996), concerning the potential benefits of home visits made by community pharmacists to housebound people, a structured visit report was developed as the instrument of the data collection. Sixteen community pharmacists volunteered to visit the referred patients at their homes. Of the 39 patients that received domiciliary visits, 35 cases showed discrepancies in the patient's own medications between those they were currently taking and those listed in the GP patient medication record. Discrepancies were due to three main factors: non-adherence, medication hoarding, and adverse drug reactions. The visiting pharmacist perceived that the domiciliary visits had been of benefit to the patients, the GPs and the pharmacists themselves. Schneider and Barber (1996) summarized in this study the benefits of domiciliary service perceived by the pharmacists as:

- Benefits to the patient
    1. Receiving a full explanation of their medication, including administration and dose regimen.

2. Understanding of medication-related problems.
3. Receiving advice on the most appropriate way of storing the medications and disposing unwanted or expired ones.
4. Improving adherence and confidence.

- Benefits to the General Practitioner
    1. Awareness of specific patients' problems.
    2. Feedback they received was appreciated for patient's medication assessment.
    3. It is quite helpful to have another health care professional visiting the patient at home.

- Benefits to the pharmacists
    1. Greater understanding of patients' medication problems.
    2. Visits helped to improve professional role satisfaction.
    3. Visits helped to raise the role of the pharmacist in the community.
    4. Visits were important to improve the relationship between the prescriber and the pharmacist.

The major weakness in this study is that the domiciliary visits were not performed by the patients' own community pharmacists; it may have been more realistic if the visits had been conducted by the community pharmacists used regularly by the patient due to their knowledge of the patients and their medication. The counter argument is that a dedicated trained pharmacist would have greater clinical skills than the average community pharmacist (Foulsham and Goodyer, 1999). Also, this study focused on only one group of patients *i.e.*, housebound people with medical difficulties. It has been quite consistently observed that domiciliary visits for elderly patients can uncover a wide range of medication-related problems. This has not only been recorded by Schneider and Barber (1996), but also by Foulsham and Goodyer (1999). A pharmacoeconomic study has not yet been conducted which can truly identify the cost of providing such a service as compared to any health benefits to the patients. Such services are currently provided as according to primary care trust needs and often linked to a monitored dosage scheme. There are no schemes well

documented in the literature whereby a hospital based worker provides a discharge follow-up service regarding patient medication.

The present project aims to study the influence of domiciliary pharmacy visits from a hospital-based worker on medication management in elderly patients recently discharged from hospital to their own homes and providing them with the most appropriate pharmaceutical care. Identification, classification and prevention of the medication-related problems are the core of pharmaceutical care and are discussed in the next section.

1.3 Defining, identifying and Classifying Medication-Related Problems (MRPs)

In this section the definition, identification and classification of drug-related problems will be discussed.

Maximizing efficacy, minimizing risks, reducing costs and respecting patients' choices are the main features of good prescribing of medicines (Barber, 1995). In reality, this does not occur because medicines are sometimes prescribed inappropriately (Cantrill *et al.*, 1998) or because of inappropriate use of the prescribed medicines by the patients (McGavock, 1996). Medication-related problems (MRPs) can reduce the potential clinical benefits of treatment with medicines and waste NHS resources.

Manasse (1989) reviewed the different causes for the adverse consequences of using medication and found that adverse drug reaction rates varied widely (0.66%-50.6%). There was no clear explanation for this great variation but it may be due in a large point to the different techniques used to identify these problems. In this review it was reported that the observed percentage of hospitalizations due to adverse drug reactions seemed also to vary widely. It was concluded that up to 10% on average of all hospital admissions might be caused by drug misadventures.

The phrases "drug-related problems" (DRPs) and "medication-related problems" (MRPs) will be used interchangeably throughout this project.

1.3.1 Definition of Medication-Related Problems

There are various definitions of medication-related problems (MRPs). MRPs can be defined from a narrow perspective of adverse drug reactions and undesirable drug interactions which relate to the pharmacology of the medicine. Definitions may also describe the medicine-taking behaviour of the patient or their non-adherence to the treatment. From a wider perspective, MRPs could encompass adverse drug reactions, patient medicine-taking behaviour and problems initiated from the prescribing of medicines.

There are a number of different, but nonetheless rather similar, definitions of MRPs. Hepler and Strand (1990) chose to define it as "*an event or circumstance involving drug treatment*

that actually or potentially interferes with the patient's experiencing an optimum outcome of medical care". This definition was modified by Strand and other co-workers (1990) to "*an undesirable patient experience that involves drug therapy and that actually or potentially interferes with a desired patient outcome*". With this definition, the MRPs can only exist if a patient is experiencing the disease or symptom and the condition is related to the medicine. This definition differed from others in that the main focus was to ensure that the medicines were appropriate. A shorter definition that more clearly includes problems detected by pharmacists, besides the ones presented by the patients, is the following by Segal (1996) "*a circumstance of drug therapy that may interfere with a desired therapeutic objective*".

The Pharmaceutical Care Network Europe (PCNE), a network of researchers in pharmaceutical care, used a definition for DRPs which is quite similar to that expressed by Hepler and Strand "*an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes*" (Van Mil, 1999). Some authors have preferred to use the term "medication-related problems" (Shimp *et al.*, 1985).

Treatment with medicines should have a patient-centered approach because "*drugs are administered for the purpose of achieving definite outcomes that improve the patient's quality of life*" (Hepler and Strand, 1990). Hepler and Strand highlighted the positive outcomes of treatment with medicines which were marked by a reduction, elimination, slowing or prevention of symptoms or diseases. For an event to be qualified as a DRPs, a patient must experience or likely to experience disease or symptom and the condition must have an identifiable or suspected relationship with the drug therapy (Strand *et al.*, 1990). The main problems associated with treatment with medicines are inappropriate prescribing, inappropriate delivery, inappropriate behaviour of the patient, patient idiosyncrasy and inappropriate monitoring. Inappropriate monitoring was considered as the most important but the least appreciated, since many of these problems 'can be detected by careful monitoring (Hepler and Strand, 1990).

Drug-related problems were defined by Kaplan *et al.*, (1994) as "*problems related to drugs likely to cause clinically significant harmful effects to patients if not brought to the attention of the primary care physician*". Similarly, Akwagyriam *et al.* (1996) in a study of MRPs

presenting to a causality department used criteria which included adverse drug reactions (ADRs), dosage problems, drug interactions (DIs), compliance problems, drugs not properly documented on an accident and emergency (A&E) card and any other MRPs identified by the A&E senior house officer. These definitions have relied on the clinical experience of the physician.

Strand *et al.* (1990) proposed a patient-focused definition to enable the pharmacist to have a "*tangible impact on actual patient outcomes*". Similarly, other authors have concluded that the pharmacist has a professional responsibility to detect medication-related problems and contribute to patient outcomes. Granas and Bates (1999) defined MRPs in a study of repeated prescribing* as "*any problem with the prescribed medication that the community pharmacist considered was not good prescribing practice*". However, there has been some evidence that the clinical expertise of doctors and pharmacists has been shown to differ and there has been some evidence of disparity of both healthcare professionals have rated the severity of medication administration errors as stated by Dean (1999). This may be applicable to any medication-related problems not only on repeat prescribing, and it may be reasonable to involve both doctors and pharmacists in the process of identification and assessment of MRPs.

This section has focused on the range of definitions of medication-related problems reported in literature. The following section will discuss the identification and classification of medication-related problems.

1.3.2 Identification of Medication-Related Problems

As mentioned in the previous section, in order for an event to be identified as a MRP, two conditions must exist (Strand *et al.*, 1990):

1. Patient must experience or be about to experience a disease or symptom.
2. These diseases or symptoms must be identified to be related to a drug therapy.

* A repeat prescription is the issue of a prescription for a medicine, without a consultation, to patients on long-term medicines (Zermansky, 1996).

Lee and Beard (1997) reported the frequencies of patients with adverse drug reactions (ADRs) in the community. It was found that there was as wide variation between the estimates of the ADRs as 2.6-41%, but they did not report the sources of these figures and this variation may be attributed to the differences in the methods used to detect suspected reactions and differences in the definitions. Lower percentage of 2.6% can be attributed to MRPs identified during GP consultations. The frequency of patients with MRPs may be as high as 65% when the patients are interviewed in their own homes in comparison with reviewing the information from their records (Mulroy, 1973).

Two literature reviews (Sullivan *et al.,* 1990 and Einarson, 1993) which reported medication-related admission concluded that 5% of all hospital admissions were medication-related, despite using different definitions of MRPs. Sullivan *et al.* reviewed seven studies for non-compliance defined as overuse, underuse or erratic use of medicines. Einarson (1993) reviewed 36 studies for MRPs which were categorized as adverse drug reactions (ADRs), drug interactions (DIs), mistaken drug use, inadequate or improper therapy and exacerbation of disease resulting from medication non-adherence. Another study (Lamour *et al.,* 1991) has reported a frequency of patients with MRPs to be as low as 2.4%. Lamour *et al.,* (1991) found that 136 (2.4%) of 5,623 hospital admissions were attributed to ADRs. This low percentage was mostly based on detection of ADRs or restricted definitions of MRPs. A higher percentage was identified in a study by Col *et al.* (1990), who interviewed 315 elderly patients admitted to an acute care hospital to determine the percentage of elderly hospital admissions due to non-compliance with medication regimens or adverse drug reactions. Eighty-nine of the elderly admissions (28.2%) were drug related, 36 were due to non-compliance (11.4%) and 53 were due to adverse drug reactions (16.8%). This leads us to the conclusion that the variations in MRPs frequencies are related to the definition used and also can be related to the confusion between ADRs, MRPs and the compliance.

Patient medication records (PMRs) and prescription monitoring is one of the methods that can be employed to identify any MRPs patients may experience. The position of pharmacists at the interface between distributing the medications and patients using them makes their role in preventing inappropriate prescribing problems important (Rupp *et al.,* 1992). The pharmacist's ability to monitor prescriptions in order to detect incidents defined as "*all*

possible medication and prescription-related problems that might be encountered by a community pharmacist" including those arising from the purchase of OTC or pharmacy recommended medication was investigated by Greene (1995). A survey of prescription problems was conducted in 23 community pharmacies. A report form was designed for the community pharmacists to record each incident detected and was rated according to its clinical significance as: 0 for trivial incidents; 1 not serious; 2 serious and 3 very serious. These incidents included the frequencies patients presented with prescription, a changed drug or dosage form, a changed dose or timing, inappropriate dose or timing, a drug-drug interaction and a drug-condition interaction. Three hundred and forty incidents were reported, 16% were classified as very serious, 48% as serious, 26% as not serious and 10.9% were classified as trivial. The very serious incidents included haemorrhage from excess warfarin and uncontrolled hypertension with the risk of a stroke. The serious incidents included overdose and duplication. The less serious problems included prescriptions requested too early but with a reasonable explanation. Finally, examples of trivial problems included the change of the prescription from cream to ointment form. This study identified a higher frequency of serious incidents and this may be attributed to the design of this study encouraged pharmacists to record more serious problems. Note that the judgment for severity was made as a subjective assessment by the investigator alone.

In a study by Rupp *et al.*, (1992), the interventions performed by 89 community pharmacists to correct the prescribing problems they identified on new prescriptions were documented. Four types of errors were recognized. '*Errors of omission*' were defined as errors where the prescription lacked important information or the information was vague or unreadable. Examples of this type of error were inadequate specifications of dosage or strength, quantity or duration not specified and prescriptions being illegible. '*Errors of commission*' were defined as an incorrect strength or dose, and were potentially serious and harmful and represented a threat to the patient's health. Examples representing this category were the prescribing of an inappropriate dose or inappropriate strength, incorrect form or quantity or incorrect patient. The third form of error was drug-drug interaction or drug-disease interactions. The last form was Others which includes patients' concerns or fraud prescriptions. Community pharmacists managed to make interventions on 683 prescription errors out of 53,941 prescriptions dispensed in the community pharmacies. Three hundred

and twelve (46%) were errors of omission and 249 (36%) were errors of commission. Other errors identified were 8% drug interactions and 10% miscellaneous problems, which included any questions or concerns that patients had about their medicines. Only 1.9% of these prescriptions showed problems needed to be acted upon, this may be due to the fact that the review was performed on the new prescription orders.

It is difficult to rely on the prescription monitoring by the community pharmacists as a sole tool for identification of MRPs, as patients may be filling their prescriptions from more than one community pharmacy. In addition, pharmacists do not keep any records of the patient's clinical diagnosis or laboratory results. The data stored on pharmacy records are mainly a reflection of the information presented on prescriptions and any information offered by patients. The information that appears on prescriptions should correspond to the information held on computerized medicine histories in GP surgery. Therefore, prescriptions can potentially be used to confirm the information held on GP surgery records and patient medical records in GP surgeries can be used as another tool for identification of MRPs. The main advantage of using GP surgery records to identify MRPs is that patients normally use only one GP surgery, therefore all their medical information is held at one location. GP surgery records can also provide data on the diagnosis for which the medicine was prescribed and the patient's clinical status. For patients who are on long-term treatment for chronic illnesses, repeat prescriptions are issued from GP surgeries. One disadvantage of using repeat prescriptions is that they may themselves resulting in MRPs due to inadequacies of GP records; for example, patients can restart medicines that have been already stopped (Corbett, 1995).

Granas and Bates (1999) reviewed 511 prescriptions for patients taking three or more medicines. One hundred and eighty seven prescriptions of the 511 (37%) were identified as having MRPs. Of those 187 prescriptions, 90 repeat prescriptions were assigned to a trial group with pharmacist intervention. Of those 90, the GPs agreed to respond to 77 (86%) of the pharmacist's recommendations. In this study the GPs agreed on a higher number of recommendations made by the pharmacist. This was possibly due to the prospective nature of the study which meant that prescriptions were written on the same day and they were able to assess what medicines the patients were actually being prescribed and were possibly taking.

This high agreement was attributed to the nature of the intimate relationship between the GP and the pharmacist where there was only one GP/pharmacist pair who took part in interviewing the major proportion of repeated prescriptions.

In another study (Goldstein *et al.*, 1998), volunteer pharmacists reviewed notes for patients with 6 medications or more who were referred by their GPs. Volunteer pharmacists received training to allow them to review confidently repeat prescriptions and systems. One thousand five hundred and sixty four patients who received six or more medicines were reviewed where 13,194 medicines were reported in the patients' records. Potential problems were identified for 9,762 (74%) medicines. Discussions addressing the identified problems and possible solutions were held between the pharmacists and GPs. Three months later the volunteer pharmacists reviewed GP notes to determine whether changes had occurred. The GPs agreed with 5,628 (58%) of the recommendations but implemented the advice given for only 3,132 (32%) medicines. The reasons why GPs did not always act upon the pharmacists' suggestions included: insufficient time for patient recall between pharmacists' suggestions and their follow-up visits, GPs reluctant to alter medication which they were not the original prescribers. A further reason was pressure from patients for medication which has been previously prescribed and had perceived benefit although not clinically required *i.e.*, it was "not worth upsetting a patient". The problems identified were categorized into 11 categories including duplicate prescribing, inconsistent/inappropriate quantities, drugs no longer needed, inappropriate directions, more reasonable alternative drug choice was available, possible drug interactions, suspected compliance problems, further investigation required, side effects and drugs prescribed outside their product license. This study did not investigate MRPs due to poor patient knowledge. The high frequency of MRPs identified by Goldstein *et al.* (1998) could be explained by the inclusion criteria, which targeted patients who were more at risk of MRPs because of taking six or more medications. The nature of the relationship between the GP and the pharmacist may have been less intimate compared to Granas and Bates (1999) since there was 47 GP/pharmacist partnerships formed in Goldstein *et al.* (1998) compared with the one GP/pharmacist pair in the Granas and Bate (1999) study.

A review of patients' records kept at the surgeries relies on what has been documented which means that these records may not necessarily be able to reflect what patients are actually

taking in their homes or explain how they manage or store their medicines. Interviewing patients can be considered as a useful tool to find out what medicines they are actually using, how they use these medicines and how they store their medicines, how they respond to the therapy and consequently uncovering any medication-related problems.

The previously mentioned '*Brown bag*' medication reviews can be used as an effective and potential cost-effective tool to uncover medication-related problems, which may not readily come to the attention of the GP. These reviews can enable the GPs and the pharmacists to be aware of problems that patients may encounter with their medicines. Interactions between prescribed medicines and OTC products is one of the areas that can be identified by such reviews, as GPs are normally not aware of what patients buy over the counter for self-treatment of minor ailments (Nathan *et al.,* 1999). The main disadvantage of this scheme is that the efficacy of the review depends mainly on what the patients choose to bring with them to the session.

Domiciliary visits can be another tool to identify MRPs that might be missed by other means. In one study (Foulsham and Goodyer, 1999), 90 patients (with age range from 26-96 years) received domiciliary visits. Patients were visited by the community pharmacist in response to referrals from GPs, social services or district nurses. Reasons for the referrals included a range of problems that were directly related to the use of medicines, for example, administration problems, taking three or more medicines or taking medicines on more than two occasions per day, or there was an evidence of poor adherence due to a lack of review. Other reasons for referring a patient included: recent hospital admissions, interface problems, the patients' need for explanation of the purpose of medication, or when repeat prescriptions were requested irregularly or not often enough. Eighty four (93%) of 90 patients visited were identified with one or more medication-related problems. A potential limitation of this method is that the identification of the medication-related problem can be influenced by the subjective view of the visiting pharmacist. Also, results of this type of medication review depend upon what the patients bring to the consultation.

Similarly, Schneider and Barber, (1996) reported the medication-related problems identified by 16 community pharmacists who made domiciliary visits to 39 patients referred by 14 GPs.

Thirty-two patients were identified as having one or more discrepancies attributed to one of three factors. These factors were non-adherence, inaccurate medication record and hoarding. 16 (41%) reported adverse drug reactions (ADRs). These ADRs included nausea, constipation, diarrhoea and stomach upset due to NSAIDs, Opioid analgesics and iron. Also, cases of incontinence caused by diuretics and drowsiness caused by benzodiazepines were reported. Eleven cases of drug interactions were identified by the community pharmacists. The majority of these cases included Paracetamol toxicity (due to taking more than one product containing Paracetamol at the same time); ulcer exacerbation (taking NSAIDs while taking H_2- antagonist for the treatment of ulcer). Other problems reported in this study included: difficulties in reading labels, problems in opening child-resistant containers, using more than one container or package for the same medication and mixing or transferring medications in different containers.

From the above, there are a wide variety of methods for identifying medication-related problems. These methods include reviewing patients' medication records, prescription monitoring in pharmacies, patient medical notes in GP surgeries and patient interviews either in their homes, or in the community pharmacies or any other convenient setting. It would appear that researchers construct their own classification systems making comparison between studies quite difficult. By far, the most important drawback concerning bias and generalisability of such studies is that the judgment concerning the presence of MRPs is often subjectively made by the researcher or team. This is particularly relevant when attempts have been made to assess the "seriousness" of MRPs. Therefore, the validity of the findings of many of these studies could be called into question. A potential solution might be to identify a classification scheme with precisely stated criteria that has been employed by a number of studies. A second important area to address is the judgment of the MRPs ideally by a panel of healthcare professionals but at least by one or two other independent observers. The following section examines these points.

1.3.3 Classifications of Medication-Related Problems

As mentioned previously, the "*medication-related problem*" is very broad in its definition. There is no universal classification of drug-related events but classification of MRPs is important when assessing the effectiveness of pharmaceutical care services.

There are a variety of ways in which MRPs have been classified. In some classifications, the causes of MRPs are separated from the problems. In other cases, classifications of the MRPs describe the causes behind these problems. Other classifications consider the interventions being employed to reduce these MRPs. The most widely used categorization system was the Strand *et al.* (1990) classification and is most often referred to as the 'Strand Classification'. In this system, the term "*drug-related problem*" was introduced and divided into eight basic categories:

1. There is a medical condition which requires medical therapy (indication) but the patient is not receiving any medicine for that indication. This category includes interruption of the drug therapy and not prescribing prophylactic treatment against certain condition.

2. The patient has a medical condition but the wrong medicine is being taken. This category includes prescribing ineffective or less effective therapy or prescribing drug therapy when an allergy or contraindications exist. This category includes also prescribing the more expensive drug.

3. The patient has a medical condition for which too little of the correct drug is being taken. This category includes prescribing drug with inappropriate dosing interval or for a period not long enough to achieve the desired outcome.

4. The patient has a medical condition for which too much of the correct drug is being taken.

5. The patient has a medical condition resulting from an adverse drug reaction.

The patient has a medical condition resulting from a drug-drug, drug-food, and drug-laboratory interaction.

6. The patient has a medical condition that is the result of not receiving the prescribed drug. This category includes patient noncompliance, inability to buy the medication, indolence, technical problems with devices used and formulation problems.

7. The patient has a medical condition resulting from taking a drug for which there is no valid indication.

This classification focuses mainly on the events that caused *actual* harm to the patients, which means it can not be used effectively to classify events that are *likely* to cause harm to the patients. This means that this system is not able to classify potential DRPs and to help prevent any harm a patient may be exposed to before the harm occurs. A further drawback of this classification is the failure to specify the causes (mechanisms) of the drug-related problems which is important to be able to prevent the recurrence of the problem itself. Finally, the system would not detect the presence of some important problems, like therapeutic failures, lack of knowledge and drug abuse.

In a trial to overcome some of these problems, a further classification was suggested by Wills and Brown (2000). This classification highlights the relationships between different drug-related events (DREs). Drug-related event can be classified as "any incident involving at least one drug and a patient or healthcare professional" and classified into two major classes:

A. Procedural DREs

This class concerns the procurement of medicines and the procedures of supplying them, including prescription-writing requirements. For example, if a doctor forgets to sign a prescription, this may not cause direct harm to the patients, but the absence of the signature may cause a delay in delivering the medicines in time which in turn causes a delay in therapy. This class also comprises of errors in clinical trials documentation and drug administration records.

B. Clinical DREs:

This class concerns the events in which the drug itself is the corner stone that directly or indirectly affects the patients and their health. This class is divided into two main categories;

beneficial and detrimental DREs. The beneficial category includes (in contrast to normal classifications the useful events rather than the harmful ones) the actions (interventions) which are helpful to the patient's healthcare, *e.g.*, successful response to a treatment, patient counselling, appropriate drug selection and accurate drug dispensing. The detrimental category includes the undesirable events caused by certain drugs. This category is comprised of eight basic types: adverse drug reactions, adverse drug interplays (drug interactions or incompatibilities), overdose (accidental or non-accidental), prescribing errors (drug choice, dose or frequency, route or method of administration, regimen changes or monitoring deficit), errors in interpretation of the prescriptions (administration errors or supply errors), non-compliance, unavoidable non-responses and abuse.

This classification is meant to be simple, comprehensive and easy to understand and use. However, it is difficult for any system to be comprehensive as there are such a wide range of events to be included. The reasons for these difficulties stem from the fact that many of the events cannot easily fit into a 'tree structure' classification which is one of the requirements to constitute a suitable classification system (Schaefer, 2002). The other reason for these difficulties is that individual events can be related to more than one cause, making its allocation in one category challenging. Another weak point regarding this classification is the absence of a category for the physical difficulties patients may suffer that could have a bearing on MRPs. The last drawback of this system is the failure of this system to cover problems related to patients' knowledge about their medication.

In Sweden, a different classification was employed in a study carried out by Andersson *et al.* (2003). This classification is based on linking the patients' MRPs to the pharmacists' interventions where a self-reporting system was used by pharmacy staff in Swedish community pharmacies. Medication-related problems and interventions were documented using a self-completed card; one side of the card being used for reporting patient's demographic data and drug-related problems. More than one problem could be marked on the same card but only one card can be used for each drug. The other side of the card was used to document the interventions by the reporting pharmacist and more than one intervention could be marked per card. Medication-related problems were defined as "*a circumstance of drug therapy that may interfere with a desired therapeutic objective*" and intervention was defined

as "*any kind of measure taken by the pharmacy staff members to solve a detected drug-related problem*". MRPs were classified into 16 categories:

- Uncertain purpose of the medication
- Incorrect use or handling of drugs
- Inappropriate self-care
- Drug interactions
- Side Effects
- Lack of effects
- Drug duplication
- Prescribing errors
- Difficulties in swallowing tablets
- Difficulties in opening containers
- Other practical problems
- Under-dosage
- Over-dosage
- Language problems
- Problems caused by the pharmacy
- Others

Interventions were classified into 11 categories:

- Improving patient's understanding of the therapy
- Solve dosage problems
- Select appropriate medicine
- Contact prescriber
- Improving patient's practical handling of medicine
- Recommend patient to contact doctor or nurse
- Eliminate side effects
- Eliminate interactions
- Information in relation to patient's disease
- Problems not solved
- Others

This classification is based on an earlier system from Sweden called the '*Westerlund System*' (Westerlund *et al.*, 1999). The system includes an intervention classification and a manual for its use. This classification based on Hepler and Strand's (1990) definition of the MRPs as "*a circumstance related to the patient's use of a drug that actually or potentially prevents the patient from gaining the intended benefit of the drug*".

This system was classified to be used by different pharmacy personnel *i.e.*, pharmacist, prescriptionist* or technician to detect MRPs in patients of all ages. A form of different options of types of problems, based on the principal investigator's own professional experience was constructed. A special data collection form was designed to document:

- Type of problem (14 categories).
- Type of intervention (11 categories).
- The name of the drug causing the problem.
- The way the problem was reported whether by the patient or by the pharmacist.
- Patient's gender and age.
- The number of prescribed medicines.
- The time taken to respond to the problem.

The form was produced as a postcard, printed on both sides and should be filled after the patient leaves the pharmacy. A card was used for each problem per patient. The different identified MRPs were categorized into 14 different classes:

- Unnecessary aim of drug
- Underuse of medication
- Overuse of medication
- Other dosage problems
- Drug duplication
- Drug-drug interaction
- Therapy failure
- Side effect
- Difficulty swallowing tablets
- Difficulty opening container
- Other practical problems
- Language deficiency
- Prescribing error
- Other MRPs

This system correlated the identified problems to the interventions performed to solve these problems. Interventions needing to be performed are classified into different 11 categories:

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* In Sweden, prescriptionists have shorter university education but have the same legal rights and obligations regarding prescribed medication as pharmacists.

- No intervention
- Patient medication counselling
- Practical instruction to patient
- Prescriber informed only
- Prescriber asked for information
- Intervention approved by prescriber
- Intervention disapproved by prescriber
- Switch of drug
- Referral to colleague
- Other intervention

Another classification system was described in a study by Dean and Barber (1999) where 30 healthcare professionals from four UK hospitals identified 50 medication errors. Three categories were used in this study; *minor* (very unlikely to have any adverse effects), *moderate* (likely to cause some adverse effects or may interfere with the therapeutic goal of the regimen but very unlikely to result in death or lasting impairment), and *severe* (likely to cause death or permanent impairment). This judgment was based upon the assessment by a panel of blinded healthcare workers.

It is believed that inappropriate medication prescribing is a common problem among the elderly and has been associated with unnecessary medical expenditure *e.g.*, adverse drug reactions, morbidity and health services utilization and drug-related hospital admissions and readmissions (Lindley *et al.*, 1992). The Medication Appropriateness Index (MAI) was developed as a tool that "*uses explicit criteria to make implicit judgments about medication appropriateness*". The tool was designed to assess multiple elements of drug therapy prescribing and appropriateness of medications and requires that a medical history problem list and medication list is available for review. The index is made-up of ten criteria regarding medication indication, effectiveness, dosage, directions, drug-drug interactions, drug-disease interactions, expenses, practicality, duplication and duration. These ten criteria are worded as questions such as "*Is there an indication for the drug?*". The questions are answered using a four-choice scale where A is indicated, B is marginally indicated, C is not indicated and Z in not known and given a score between 0 and 18 is being increasingly inappropriate. The MAI comes with general instructions about the best way to use the index and to answer the ten questions (Hanlon *et al.*, 1992).

The most recently published classification system is the one used by Sorensen *et al.* (2003) where a "quality use of medicines" coding system was developed to assess the appropriateness of pharmacists' medication reviews. A total of 19 codes were developed from literature based on previously identified medication-related problems. The coding system was evaluated for inter-rater reliability using three raters (Hospital pharmacist, pharmacist specialized in medication review in a nursing home and a research pharmacist). The codes used are: adverse response AR (+/-), interactions INT (+/-), contraindication CI (+/-), sub-therapeutic dosing ST (+/-), overuse/toxicity TOX (+/-), essential therapy ES (+/-), polypharmacy PF (+/-), good clinical pharmacy practice GCPP (+/-), mortality M (+/-) and clinical non-significant code CNS (+/-). To assess the practical effect of this coding system, it was applied to 216 medication profiles (111 interventions and 105 controls) by an independent clinical pharmacist with the aim to assess the appropriateness of pharmacy interventions. Although one medication can be involved in more than one intervention, underestimation of the number of interventions may occur as this system depended mainly on assigning one medication with one code. Also it was sometime difficult to identify whether the intervention was initiated by the doctor or the pharmacist.

The last classification system adopted in the current study is the PCNE system which was developed by the Pharmaceutical Care Network Europe. Details of the classification itself, validation and categories will be discussed in Chapter 3.

In conclusion, it appears that there are various definitions given to drug-related problems. Medication-related problems include adverse drug reactions, drug interactions, inappropriate prescribing and patient's non-compliance. MRPs decrease the clinical effectiveness of medicine and consume NHS resources. There is no universal classification system for the medication-related problems and different systems have been developed and employed in various clinical situations. Some of the systems used, including the Strand classification, separated the causes of the problems from the problems themselves. The Wills and Brown system highlights the relationship between different drug-related events. Westerlund/Anderson systems link the patients' drug-related problems to the pharmacist interventions. MAI was developed to measure elements of appropriate prescribing. Then

there is the simple classification system used by Dean which classified the MRPs into three categories of severity. There is also, the Sorensen classification which evaluates the quality use of medicines and provides an assessment of pharmacist medication review recommendations.

In the present study, patients will be visited in their homes and their medication will be reviewed to identify any possible MRPs and patients will be interviewed to identify the problems they suffer. The effect of improving the transfer of drug-related information from secondary to primary care on reducing the number of MRPs experienced by elderly patients will also be assessed. Two classification systems will be used in categorizing the MRPs identified through out this study. The Dean system will be used because of its simplicity, its clear definitions of its categories, the ability to score these categories and measure its severity in addition to its ability to measure service-related problems. PCNE will be used because of its ability to link the clinically identified problems to its causes and to the interventions. This is in addition to the fact that this system has been used and validated previously.

1.4 Compliance and Patient Knowledge

One of the most common MRPs observed in elderly patients is non-adherence to the prescribed regimen either intentionally or non-intentionally. This section will cover compliance from various aspects, including definition, factors, assessments and methods for improving compliance.

Compliance has been defined as: "*the extent to which a person's behaviour (such as taking medication, following diets, or changing lifestyles) coincides with medical or health advice*" (Sackett and Hayes, 1976). With such a definition, patients have little say in the treatment they receive which is contrary to the current concepts regarding patient choice in healthcare. This definition of compliance implies that *'the doctor knows best'* and that his/her decision should be the final. The role of the doctor is to decide on the appropriate treatment and issue the relevant instructions, whilst the role of the patient is to comply with the doctor's orders (Horne, 2001a). The term '*adherence*' has been suggested to replace the term '*compliance*', implying that "*it is acceptable that the patients can have the right to decide whether or not they will be able to follow the treatment regimen dictated by the prescriber*" (Goodyer, 2002) and that failure to do so should not be a reason to blame the patient (Horne, 2001a). The two terms *i.e.*, compliance and adherence will be used interchangeably the current study.

Concordance is a new philosophy in the process of prescribing medicines and improving adherence. Concordance is defined on the concordance website as "*an agreement reached after negotiation between a patient and a healthcare professional that respects the beliefs and wishes of the patient in determining whether, when and how medicines are to be taken. Although reciprocal, this is an alliance in which the healthcare professional recognizes the primacy of the patient's decisions about taking the recommended medications*". This term has been used to indicate the degree to which the patient and the prescriber agree about the nature of the illness and the need for treatment (Horne, 2001a). Concordance differs from both compliance and adherence in the that it focuses on the process and outcome of a medical consultation and has an underlying ethics of a shared approach to decision-making rather than just observing the patient's behaviour toward the medication (Weiss and Britten, 2003). Concordance is based on the principle that, patients' beliefs should be considered and

patients must be given the chance to decide the best approach to the treatment of the individual despite the difference between the patient's health beliefs, and those of the healthcare professionals. Concordance is a multi-task term, considering the patient and the doctor. The patient's task is to express health beliefs to the prescriber and the task of the doctor is to find an opportunity for this to happen and to convey his/her health beliefs to the patient. Concordance aims at helping patients and prescribers to reach a common agreement about the diagnosis, treatment, benefit and risk and so to optimise the potential benefits of medical care (Royal Pharmaceutical Society, 1997). The concept of concordance has not been formally studied to any great extent and is still not widely accepted by the healthcare professions.

Patient's compliance can be a difficult term to define and measure, as well as to determine the true extent and implications of observed compliance levels. It is also difficult to specify the level of compliance necessary to derive maximum benefit from treatment. Practically speaking, compliance is often quantified simply as the percentage of prescribed doses taken *e.g.*, using tablet counts. However, unqualified percentage figures are reported, such as: 'There was 75% compliance'. This may indicate either that the average level of patient adherence was 75%", or that 75% of patients were fully compliant with their regimens (Raynor, 1992). Ideally, levels of compliance should be specified, for each disease and treatment, below which the desired preventative or therapeutic result is unlikely to be achieved or the patient's condition is expected to show clinical deterioration. Determination of such levels is somewhat difficult especially as the majority of patients are prescribed multiple therapies. To overcome this problem, a general arbitrarily acceptable level of compliance has been proposed. It has been suggested that taking between 90 and 110% of doses is likely to produce the required therapeutic effect for most classes of the medicine (Lorenc and Branthwaite, 1993). Eagleton *et al.*, (1993) considered 85-115% as an acceptable compliance level *i.e.*, patient considered to be non-complier if he/she showed a 15% or more deviation from the prescribed regimen. Monane *et al.* (1996) used 80% or more of days a patient had antihypertensive medication available (days covered) as the bench mark of good compliance. However, each study focused on a patient category and different purpose for which compliance was assessed.

Rather than using an arbitrary value, bands of compliance can be used and each band describes the proportion of the patients falling within that level. This method can be useful when analyzing the effects of an intervention to improve compliance, *e.g.*, medication counselling. Pullar (1991) has categorized the patient's compliance into four categories based on four-percentage ranges. He suggested that those taking 90-110% of doses prescribed are *fully* compliant, 50-89 as *sloppy* compliers, 30-49% as *low* compliers and less than 30% as *non-compliers.* Anderson (1987) used less than 75% as a poor compliance level, 75-90% as fair compliance and greater than 90% as good compliance level.

McElnay *et al.* (1997) reported a useful compliance description system:

- *Partial compliers*: those who take between 40 and 80% of the prescribed dose and this is representing one third of the patients.
- *Satisfactory compliers*: those who sometimes take more and sometimes take less than the dose prescribed and are representing one third of the patients.
- *Poor compliers*: those who take less than 40% of doses prescribed at widely varying intervals and are representing one sixth of the patients.
- *Good compliers*: people who hardly miss a dose and only occasionally take extra dose and are representing one sixth of the patients.

The problem of poor medication compliance to the prescribed regimen and knowledge has been reported in numerous studies. There are many factors that may influence patient's compliance (Col *et al.*, 1990):

a. Patient's perception of the seriousness of the condition being treated and patient's beliefs regarding the risk inherent in their diagnosed disease compared with the benefit of treatment.
b. Patient's satisfaction with the treatment regimen offered.
c. The way the patients being supervised by their clinicians and reluctance to listen to their concerns.
d. Complexity of the drug regimen.
e. Adverse drug events patients may suffer and may discourage them to continue using their medication.

f. Package of the drugs (difficulties in opening bottles or taking the tablets out of the blisters) and difficulty in administration, particularly for complicated devices such as inhalers.
g. Cognitive function and mental abilities of the patients.
h. Advancing age.
i. Patient's knowledge and information.
j. Disability/physical function
k. Using more than one pharmacy.

Of all these, it is the complexity of the prescribed regimen which has been shown to have the greatest influence on compliance (Eagleton *et al.,* 1993).

Patients may be harmed due to their non-adherence due to receiving sub-therapeutic levels of the prescribed medications. In other circumstances, unnecessary medication may be prescribed because non-adherence to prescribed medication is interpreted by the prescriber who is unaware of the non-adherence as a need for more medication (Rosen *et al.,* 2004).

'*Deliberate non-compliance*' describes patients who consciously choose not to adhere to their medication regimens. Such behaviour is the most difficult to address, as patients cannot be forced to comply (Raynor, 1992). Attempts to identify and change the underlying factors which cause the patients to choose not to adhere are difficult and time-consuming. '*Deliberate non-compliance*' can sometimes be useful behaviour *i.e.,* it may be in the patient's interest not to comply with the physician's directions for example, the use of analgesics, laxatives and sedatives only when needed, even if the medicines are prescribed to be taken regularly. This term leads to another term '*intelligent non-compliance*' which describes the patients who alter their prescribed therapy without suffering any adverse consequences. There are many reasons for this attitude: wrong diagnosis may be made, patients recover from illness despite poor compliance and patient's belief that the prescribed medication is causing side effects (Stewart and Caranasos, 1989).

Goodyer (2002) described in his review another term '*drug –holidays*' which is used to describe the situation "*when drugs may be taken strictly as prescribed then omitted completely for few days*". This concept introduces another term referred to as '*white-coat compliance*' in which compliance improves for certain period before a scheduled medical examination (Feinstein, 1990).

1.4.1 Compliance and Drug Knowledge in the General Population

In this section of the review some of the studies which describe the extent, and some of the factors influencing drug compliance and knowledge will be examined in more detail.

Studies Examining General Compliance Levels

Non-compliance with prescribed medicines is widespread, and it significantly compromises the wellbeing of patients. Parkin *et al.* (1976) found in his study that, half the patients he recruited were deviating from prescribed treatment because of either non-comprehension or non-compliance or both. Deviation from prescribed treatment may be due to failure to understand the nature of the regimen (non-comprehension) or lack of adherence to the treatment even when the correct regimen is known (non-compliance). Interviewing patients can determine which of them do not know what drugs to take or when or how, but patients who are non-compliant may not admit the fact on interviewing.

McElnay *et al.* (1997) carried out a study reporting patients' adherence with prescribed medications in a population of elderly patients prior to their hospital admission. Five hundred and twelve patients self-reported their compliance patterns, 13.7% of this population reported non-compliance. The percentage of under-compliance was 10.7% with 4.3% reporting over-compliance. However, it is well recognized that self-reported non-compliance is probably a gross underestimate of actual non-compliance. On the other hand, Blenkiron (1996) found when he interviewed 80 patients aged 75 years and over to assess their level of compliance. Patients claimed to be "good" compliers *i.e.*, never miss a dose, for 77% of prescribed medication. Compliance may decrease in the intervals between visits to clinic or outpatient department, this reduction may be due to poor recall of information. In 20 epileptic patients monitored using hidden microelectronic device (Cramer *et al.*, 1990) compliance fell from

86% just immediately after the visit to 67% one month later. Epilepsy is a chronic disease in which drugs must be administered over a long period of time, although seizure may be produced as a complication of the non-adherence of therapy. Even so, compliance levels as low as 39% for more complicated regimens have been reported. In another study carried out in cardiological department in a teaching hospital in Germany, it was reported that the most important factor leading to hospital admission for heart failure patients was non-compliance with the prescribed drugs. Non-compliance was reported in 23.5% of the monitored patients (Michalsen *et al.*, 1998).

Several factors combine to produce patient compliance. These factors will be discussed in the following section

Factors Affecting Compliance

Nonadherence to treatment occurs for a variety of reasons including: doubt over the expected benefits and its effectiveness; real or perceived barriers including side effects; unique demands of the regimen itself and lack of help and support from family members or carers (DiMatteo *et al.*, 1993). Clinical depression also can be considered as one of the reasons behind non-adherence, probably because of the sense of hopelessness, social isolation, fatigue, and impairment in cognitive focus that accompany depression (DiMatteo *et al.*, 2000). Recent qualitative research also pointed to patients' identity and self-image, and the meaning of medication, as important factors affecting patient's adherence to medical advice (Lambert *et al.*, 1997).

The disease in which adherence and persistence have been best studied is hypertension, and it can serve as a useful model of chronic drug therapy. About half the people with hypertension receive drug treatment; around half of them have well controlled blood pressure and half stop taking their drugs during the first year of treatment. Hypertension as a disease causes no symptoms and often needs more that one medication to control it with various adverse side effects (Bloom, 2001). Hypertension therapy in particular (Sackett, 1980) is identified as a disease with notoriously low level of medication compliance with only about one third taking adequate medication to control blood pressure. This author pointed out that the treatment of

hypertension carries all five of the major reasons for poor compliance: long duration of treatment; complex regimen; absence of symptoms; drugs with many side effects and adverse 'health beliefs' regarding high blood pressure. On the other hand Bloom (2001) reported that compliance with antihypertensive drugs is better in older patients, women, and in those prescribed fewer drugs. Similar results were reported by McElnay *et al.* (1997) where diuretics in particular were negatively associated with poor compliance.

The seriousness of the condition as experienced by the patient is a particularly important factor. Diseases such as diabetes or chronic heart failure are conditions where the consequences of non-compliance may be obvious (Eraker *et al.*, 1984). The perception of the seriousness of disease is well illustrated in a trial described by Krall (1991) where the same medicine was given to patients whether suffering from angina or hypertension. The health perception scores for hypertension are lower than those for angina and compliance in the hypertensive group was found to be correspondingly poorer. Patients with angina may perceive their heath as compromised while patients with hypertension may be believe that the hypertension has little impact on their health.

Eraker *et al.* (1984) compared compliance behaviour to short-term medications and long-term medications. It was found that compliance in short-term medicines was around 90% compared to chronic medication at 50%. They argue that in many cases of poor compliance a health decision or belief model is adopted by the patient which will determine compliance. This will depend upon many factors: medication preferences; health and other beliefs; previous experience and knowledge and other sociological factors.

It is always believed that the more complex the medication regimen, the less likely that the patients will comply *i.e.*, the complexity of prescribed regimen may result in introduction of non-intentional non-compliance or '*innocent*' concept (Raynor, 1992). Forgetfulness is a natural human behaviour: the more complex is the drug regimen, the more difficult it is for the patient to remember or follow the instructions (Col *et al.*, 1990).

The effect of the frequency of doses per day on adherence has been well examined and many studies summarized the effects of daily medication regimens on adherence and persistence with treatment. Blom *et al.* (1998) studied five hundred and twenty seven patients diagnosed with arthritis who were prescribed nonsteroidal anti-inflammatory drugs (NSAIDs). The study found an inverse linear relation between the numbers of doses administered daily and patient's adherence. Compliance was 78% for once a day dosing, 72% for twice, 64% for thrice, and 60% for four times a day.

Similarly, Eisen *et al.* (1990) monitored the relationship between the prescribed dose frequency and the patient's adherence to the drug regimen. One hundred and five patients on antihypertensive medications were monitored for their compliance using special containers that record compliance electronically. Patients on a once-daily dose regimen were found to remove the prescribed number of doses on 83.6% of days, while patients on two- or three-times daily dose regimens removed the prescribed number of doses on only 74.9% and 59% days respectively. It was concluded in this study that the frequency of dosage had a large influence on compliance. These results supported those reported by Pullar *et al.* (1988) where pharmacological indicator (low-dose Phenobarbital) and tablet count were used to assess the effect of dose frequency on patient's compliance. Compliance was best on a once-daily regimen, but the compliance with a twice-daily regimen was very similar, and both were superior to dosing three times a day. These results would encourage the prescribers to select the drug regimen that provides the lowest daily prescribed dose to improve patient's adherence.

Eagleton's findings (1993) suggested that the prescribing of complex regimens, when four or more medicines are prescribed, may be a factor associated with patient's non-adherence. The effect of the regimen on a patient's lifestyle, and the ease with which it can be accommodated into his daily routine, is another important factor (Raynor, 1992).

Levy and Feld (1999) reported other factors which were found to affect the patient's non-adherence:

1. *Inadequate skills or information required to complete assignment.* This category includes: poor instruction, incorrect or inadequate information on medication or appointment, or loss of appointment slips.

2. *Patients do not believe that they will be helped by the prevention or intervention activity.* This category includes: dissatisfaction with the prescriber or the treatment or the clinical procedures (*e.g.*, long periods spent waiting to see the prescriber), believing that they were receiving inappropriate or incorrect medication treatment, contradictory advice from friends or contradictory information obtained (*e.g.*, from the internet), believing that the treatment was not helping or making them worse (*e.g.*, because of side effects), condition improvement and thus no further need for the treatment, alternative health care beliefs, and indifference or "lack of will power".

3. *The patient's environment is not supportive of, or interferes with adherence.* This category includes: sickness, transportation difficulties, employment or housework interference, being asleep when medications should be taken, lack of family support or illness in the family, or medication loss or intrusive regimens *e.g.*, dialysis.

A model has been introduced that focuses on people's concerns regarding their medication together with the perceived necessity of the prescribed medication. As would be expected, those who appreciated the necessity of their medication were more likely to report higher adherence. Conversely, those who had concerns regarding their medication, *e.g.*, harmful chronic effects tended to have lower adherence in a trial to minimizing suspected risk by taking less medication. It was found in one study (Lorenc and Branthwaite, 1993) that not taking tablets as prescribed was strongly related to fears of becoming addicted to the medication. This finding contradicts the role of fear in the health belief model, which positively correlated the enhanced compliance with the concern about the illness.

Drug Knowledge

Patients' understanding of their clinical conditions and drug therapy is the fundamental requirement for optimal compliance. Although there is no 'gold standard' questionnaire with

which to test patient's knowledge about their medication, most methods involve asking questions about drug regimen, drug action and possible sides effects (Woroneick *et al.*, 1982).

There is a theoretical relationship between patient's knowledge and adherence, *i.e.*, improvements in patient knowledge may lead to improvement in patient's compliance. Sackett (1980) showed little improvement in patient's compliance despite increasing drug knowledge amongst hypertension patients. Similarly, Physe-Phillips *et al.* (1982) found that urine levels of antiepileptic drugs remained unchanged despite improvements in patient's medication knowledge. Both authors reached the conclusion that poor knowledge might still encourage a tendency to poor compliance.

Even if patients have good memories, they might not be given enough information to be able to adhere to their medication, even with a simple regimen. Generally speaking, verbal information is forgotten, and should be reinforced by written information (Raynor, 1992). In a survey in Southampton (Ridout *et al.*, 1986), of the 188 questionnaires sent out, over 70% of those responded had no knowledge of the side effects of their drugs and 37% were unaware of how to dispose off their medications. Similar results were observed in a large national postal survey of patient drug knowledge (Busson and Dunn, 1986) which revealed general unsatisfactory levels of knowledge amongst the UK population regarding prescribed medicines. Of the 8000 questionnaires analysed, 55% did not know the exact details of their regimen and only 20% had been informed of potential side effects. In spite of this, patients rarely sought additional information.

Levy and Feld (1999) revealed the relationship between inadequate skills or knowledge necessary to follow a regimen and non-adherence to that regimen. Reasons the patients gave for their non-adherence that fall into this category include: poor instruction; incorrect or inadequate information on medications or appointment, or losing the appointment slips. Patients can not follow the proposed regimen if they do not know what they are supposed to do, or know how or when they are supposed to do it. Prescribers should not assume without some form of checking, that a patients know how to carry out their treatment regimens.

A number of papers have described what type of drug information patients would like to receive, without addressing the question of the level of patient knowledge. Gardner *et al.* (1988) reported that patients highly valued the information provided regarding medication problems, but felt that much of the information supplied by physicians was unimportant. The attitude of patients towards being supplied with information is also important. McMahon *et al.* (1987) conducted a study on 154 patients in an outpatient clinic to determine what patients already knew about their medication and to study the extent to which patient were given verbal and written information. Most had good knowledge regarding their medication regimens, but knew very little about side effects and even fewer had been provided with any written information about their drugs. Dodds and King (1989) surveyed 500 patients in a community pharmacy and found that younger people were more likely to require additional information than older ones, and that women were more receptive to such information than men. In a study carried out by McElnay *et al.* (1997), it was found that full knowledge of medicines, *i.e.*, names, indications and doses, was reported by 23.8% of the patients interviewed. A further 12.7% could only provide the name of the medicines. One quarter managed to give the purposes of their regimes, while a further 28.7% gave the colour, shape or dosage of tablets being taken. Only 6.8% of the patients interviewed failed to provide any information about their medicines.

One study investigated the relation between age and knowledge of diabetic patients and their adherence to medical advice (Yung *et al.*, 1998). Patients were interviewed at the general medical clinic to assess their knowledge and adherence level. Patients' knowledge of diabetes mellitus and hypoglycaemic symptoms and adherence to medical advice declined with age and time and it was stressed that elderly diabetic patients should receive a continuous education programme.

It can be concluded that poor compliance may be induced by many factors but their relative importance and a consistent model has get to be fully defined.

1.4.2 Compliance and Medicine Knowledge in the Elderly

Poor compliance would be expected to be an especially difficult problem in elderly patients (Stewart and Caranasos, 1989) as the elderly have significantly more compliance barriers and higher risk factors for non-adherence than the general population. In addition, they have a higher incidence of long-term illness that leads to higher rates of prescribing and consuming more medication and developing more complex drug regimens (Herrier, 1995). Hence, elderly patients are more likely to be described as non-compliant. Elderly patients also appear to be particularly vulnerable to the adverse consequences of drug non-compliance.

General Level of Compliance in the Elderly

As the proportion of elderly in the general population is expanding, so has the importance of medicine taken by them. Some studies have shown that the elderly are more prone to drug medication errors and none of the socio-demographic variables (*e.g.*, age and social isolation) have been particularly helpful in predicting which patients would deviate from treatment.

In a study by Blenkiron (1996), 80 patients aged 75 years and over were interviewed in the surgery or at homes to assess their level of knowledge, degree of compliance, and problems encountered with their medicines. Compliance was assessed by both monitoring the cumulative demands for repeat medicines and by interviewing the patients as well. Elderly patients were claimed to be '*good*' compliers (*i.e.*, never miss doses) for 77% of drugs prescribed. When compliance according to computer records of repeat prescriptions was analysed, it was found to be inaccurate in 20% of cases. The consequences of non-compliance were reported and judged to be potentially serious or life-threatening 29% of the 31 drugs identified by computer monitoring of the repeat prescriptions, but for only 8% based on self-assessed non-compliance. However, the computer based assessment does not reflect the actual usage of the medication by the patients.

Earlier studies have considered compliance levels amongst the elderly post hospital discharge. Amongst studies describing good compliance in the elderly, Smith and Andrew (1983) showed an average compliance of 92% in 35 elderly patients. Patient compliance was assessed by tablet counts just 3-12 days following hospital discharge. It is possible that

compliance may decline considerably after this time. In addition, the population studied appeared to have closer communication than usual with the GP, 11 cases being visited very soon after their discharge. Other factors such as the policy of discharging patients with as few drugs as possible may also have played a role. A general poor level of drug knowledge was still recorded. Stewart and Caranasos (1989) reported that 65% of patients had made medication errors one week after hospital discharge and 26% had non-compliance scores greater than 15% and these results are similar to those reported by Eagleton *et al.* (1993); the risk of medication errors may be particularly high for many patients in the period immediately after a hospital stay. This may be attributed to the fact that patients were under intensive care and were not responsible of administering their medication.

Wandless and Davie (1977) studied the effect of providing standard verbal instructions given to elderly patients during their hospital stay on their compliance using tablet count technique and gave an error rate of 28% among these patients. Those proven to have errors more often, made multiple mistakes rather than a single mistake with medication. Even elderly patients within a rehabilitation ward failed to take their tablets correctly unless they were carefully instructed. In another study (Crome *et al.*, 1980) it was found that out of 51 patients studied only 33% took all doses as prescribed and 16% took none of the medication at all, resulting in an average error rate of 42%.

Hospitalisation of elderly patients, for whatever reason, can be a critical juncture; while patients may be admitted on one drug regimen, they are often discharged on another. One of the crucial factors that may affect the effective medication management by elderly patients is the fact that the flow of information is, to a great extent, dependent on the patient him/herself, who is free to take the prescription to any pharmacy they chooses (Begley *et al.*, 1997). Oborne and Dodds (1994) reported that two out of three patients take their prescriptions to the same community pharmacy, and it was suggested that immediately after discharge from the hospital the likelihood of selecting the regular pharmacy may be reduced because the patient may be too ill to be able to collect his or her own prescription and depends on a family member, a carer, or a friend.

Factors Affecting Poor Compliance in the Elderly

Over the past 25 years, numerous factors have been investigated in an effort to identify noncompliant patients. Factors investigated include demographic and sociobehavioural characteristics of patients, features of the illness, therapeutic regimens, and the patient-prescriber relationship (Stewart and Caranasos, 1989).

A recent review (Balkrishnan, 1998) examined the relationship between elderly patients' non-adherence with drug therapy and various demographic, medical, behavioural, economic, social, and medical practice-related variables. Some of the demographic variables examined included age, race, gender, income level, occupation, education level, social class, and patients' marital status. Medical variables that have been studied included severity and duration of illness, number of co-morbid conditions, frequency of use of medical services, quality of care provided and patient satisfaction with health care provider. Medication-related variables investigated included type of medication prescribed, therapeutic regimen, drug-delivery system, and adverse effects that may be experienced. Behavioural variables include physician-patient relationship, patients' knowledge about their medical conditions and their medications, self-reported compliance, and attitudes and beliefs about their health. The present review examines selected variables separately, although in most cases it is the interaction of several factors that allows prediction of elderly patients' medication-adherence behaviour.

The following section will discuss some of the factors that may influence patients' compliance to their prescribed medication regimen.

a. Demographic and Social Factors

No consistent relationship has emerged between a patient's compliance and gender, age, education level, socioeconomic status, occupation, race or marital status. Gender is not usually shown to be related to compliance issues, although a few studies have indicated that women may have more problems (Salzman, 1995). Col *et al.* (1990) also reported that elderly females were 3.3 times more likely than elderly males to be hospitalized for complications caused by mediation non-adherence. On the other hand, Coons *et al.* (1994) found no relationship between medication adherence to the prescribed medication

and the gender in a population of elderly adults taking various prescription medications. Similar results were reported by Monane *et al.* (1996) in a cohort of elderly outpatients starting on a new antihypertensive medication.

Most of the studies have focused on specific-age populations within a narrow age-range and therefore, the comparison are often between old and older patients rather than young and old patients. Most studies have used 60 or 65 years of age as a cut-off point, and no hard data exists specifically on the over 85s. A retrospective study by Monane *et al.* (1996) collected data from 4068 New Jersey Medicaid enrollees and demonstrated that advanced age (85 years) was associated with good adherence. The two possible reasons for this observation are that:

1. The higher the chance of experiencing severe diseases, the better the motivation for elderly patients to adhere to their medication regimens.
2. Elderly patients are more likely to be supported by carers.

Practically speaking, non-compliance is an issue for all ages, with each group having their own particular problems. However, the normal aging process involves a gradual decline in the cognitive abilities (visual acuity, memory, ability to understand and remember text) which are required by patients to take their medication properly (Raynor, 1992). When a wider age range is taken into consideration, some studies then tend to support lower compliance with patients aged 70 and over (Stewart and Caranasos, 1989).

Age was not an important predictor of medication adherence in many of the published studies. Coons *et al.* (1994) found no relationship between age and medication adherence in 1028 older adults who were interviewed about their medication-adherence behaviour. Sharkness and Snow (1992) reported similar results in a study of 125 hypertensive veterans.

There is also some evidence that patients living with their families are more likely to take medication than those living alone (Evans and Spellman, 1983). This fact is supported by Lorenc and Branthwaite (1993), where elderly patients who were not living alone (on

both chronic and acute medication) tended to show the highest compliance level. Conversely, it was found in another study that there was no relationship between living alone and compliance, although it failed to assess whether or not there was help from outside agencies (Blenkiron, 1996). Education and social class show no firm link with compliance.

Race may be significantly associated with medication adherence behaviour in the elderly. In a retrospective cohort study by Monane *et al.* (1996), whites were associated with significantly better medication adherence. In their study of veterans' views on hypertension and compliance, Sharkness and Snow (1992) also found white race to be significantly associated with better medication compliance.

Discharge from the hospital may also present particular problems for patients in arranging adequate supplies of the correct medication. Although a one week supply of a new regimen may be given by a hospital, house-bound patients may need much longer time to receive new supplies through a general practitioner (Monane *et al.*, 1994). Also, a being house-bound patient may result in losing communication with the community pharmacist.

b. Medical Factors

There is circumstantial evidence that general levels of adherence may be higher in some conditions than others. Sharkness and Snow (1992) reported that, elderly patients with one or more chronic illness requiring the use of multiple drugs were more likely to believe themselves in need of treatment and therefore were more likely to adhere to their medication regimens than those requiring therapy with only one drug. Monane *et al.* (1997) found that, patients prescribed more than one medicine for the same condition were as likely to be compliant as those taking single agents, while those patients who were prescribed multiple medications for different conditions showed significantly poorer compliance. These findings are in contradiction with the results of Coons *et al.* (1994) who found no relationship between the number of diseases and patients' adherence to their medication. Coons *et al.* (1994) found no association between elderly patients' self-

reported physical health and their medication adherence. However, they found a highly significant inverse relationship between psychological stress and adherence to the medication regimens. Similarly, adherence rates in acute conditions are often higher than in chronic diseases, especially when the chronic disease treatment seems to show little symptomatic improvement (Horne, 2001a).

c. Medication-related Factors

It was found that compliance to cardiovascular medication in the elderly, especially diuretics, is often quite high (Monane *et al.,* 1994). Monane *et al.* (1997) found a significantly greater probability of medication adherence among users of angiotensin-converting enzyme inhibitors, calcium channel blockers and beta-adrenergic blockers compared to thiazide users as a reference group in a cohort of elderly hypertensive patients. Salzman (1995) reported the percent of intentional non-compliance in elderly to the different groups of drugs: psychotropics (13%); musculoskeletal (60%); antibiotics (35%) and gastrointestinal (18%). McElnay *et al.* (1997) found that prescribing bronchodilators was associated with under-compliance, while being prescribed analgesics was associated with an over-compliance pattern. Sclar *et al.* (1994) have shown that the use of sustained-release formulations of antihypertensive therapy permits considerable simplification of drug regimen which in turn would improve patient's adherence to therapy.

Polypharmacy and non-compliance are major dilemmas for both physicians and elderly patients and both can mutually lead to each other. Polypharmacy may affect compliance which in turn may cause drug-related problems which may lead to prescribing more drugs. The best solution for this vicious circle is to try to reduce the number of medications prescribed, although elderly patients with multiple chronic diseases often require three or more medications. Within this group of patients, non-compliance leads to unsatisfactory clinical consequences which in turn may result in an increase in the numbers of drugs prescribed or changes in dosages of the already existing medicines (Murray *et al.,* 1993).

It can be accepted as a fact that the more complex the treatment, the lower the adherence. Complexity of drug regimen can have several forms: prescribing a large number of medications; the need to take medication at frequent intervals, difficulties in taking medication or use the medication devices (Horne, 2001a). There is good evidence that the more complex the drug regimen the more difficult is the medication-taking behaviour and that drug errors can increase by up to 15-fold when the number of prescribed items increases from one to four drugs (Stewart and Caranasos, 1989). More than two medications per day can lead to a threefold increase in the likelihood of self-reported non-compliance (McElnay *et al.*, 1997).

Col *et al.* (1990) and Coons *et al.* (1994) found that the greater the number of medications prescribed for elderly patients, the greater the medication non-adherence. However, Sharkness and Snow (1992) found that patients who took more than one hypertensive medication were less likely to depart from the prescribed regimen than were those taking only one drug. Sclar *et al.* (1993) reported that patients who are initially prescribed an antihypertensive medication requiring once-daily or weekly dosing rather than multiple daily dose had less frequent changes to their therapeutic regimens and lower use of concomitant therapy for blood pressure control (6% of patients taking once-daily therapy, compared with 11% to 16% of patients taking multiple daily doses).

d. Physician-Patient Interaction

There is increasing interest in the role of patient satisfaction as a mediator between information provision, recall and adherence (Horne, 2001a). Research has shown that patients who are more satisfied with their physician visit are more likely to adhere to their medication. Compliance with instructions is greater when patients feel that their needs have been met. Patient's adherence improves also when they feel that their physicians respect their beliefs, expectations and needs, and are able to provide them with information about their conditions and progress (Kunze, 1982).

In a study involving 46 practising physicians and 357 patients with diabetes mellitus or congestive heart failure, Hulka *et al.* (1976) found that good communication of

instructions and information provided by the physician was associated with low levels of all types of medication error including non-compliance. Monane *et al.* (1997) reported that medication adherence was significantly better in patients who had more frequent or more recent visits to their physicians. Stewart and Caranasos (1989) reported in his review that the improvement in physician-patient communication is a factor in increasing compliance, especially when it is related to increasing understanding and satisfaction on the part of the patient. Patient dissatisfaction with the clinician's attitude or the amount of information provided may affect patient's motivation towards the treatment and act as a barrier to adherence (Horne, 2001a).

e. Patients' Health-Related Knowledge and Beliefs

The relationship between patient's knowledge of their medication regimen and their adherence to it, is by no means simple or clear-cut. It is believed that patients' knowledge and beliefs about their health affect their medication-taking behaviours. It would be assumed that patients with a better knowledge and understanding of the purpose of medication and prescribed regimen would be more likely to adhere. There has been a long-running debate concerning the relationship between information given to improve patient's knowledge regarding medication and whether this has any effect on their medication-taking behaviours. Sharkness and Snow (1992) reported that male veterans who knew they would require lifelong treatment for hypertension were 1.3 times less likely to depart from the prescribed regimen than were those who unaware of this information.

The Health Belief model was proposed by Becker and Maiman (1975) to explain patients' behaviour regarding their medication. This model suggests that certain health beliefs, health-related motivations, perception of psychological and other costs recommended action, various aspects of the doctor/patient relationship and social influence can affect patient's medication-behaviour. The Health Belief model suggests that those who consider their condition to be the most serious tend to be better compliers. The model was originally constructed to account for compliance in general, and is not

specific for medication adherence. According to Cramer (1995) "*no convincing model for predicting medication adherence has been developed*".

One study (Lorenc and Branthwaite, 1993) observed that compliance was reduced among patients because of fear of illness, which is contrary to the Health Belief Model. It was suggested by Lorenc and Branthwaite (1993) that "*higher levels of fear produced denial of illness*". Compliance was also reduced when the patient had to wait a long time to see a doctor. This study also reported poor patient's compliance associated with poor patient's knowledge.

There are many instances where patients may decide not to comply with their regimen. For example, they may be taking more medication in the belief that they will recover faster, or they may choose to stop or reduce a course of treatment when the condition starts to resolve (Salzman, 1995).

Patient's medication non-adherence may be the result of a rational decision by the patient. The perceived views of others such as family, friends and doctors may also influence adherence (Horne and Weinman, 1999). Patients' concerns are usually associated with commonly held beliefs that "*taking regular medication would result in harmful long-term effect or cause dependence and that having to take medication was disruptive*" (Horne, 1993).

This section provided a variety of the factors affecting the behaviour of elderly patients towards their medication and the level of compliance. From this, it can be concluded that the highest risk factors that potentially lead to poor compliance are: poor knowledge, being female, polypharmacy and complex drug regimen, physical barriers and lack of home services. This study is focusing on improving patient's knowledge and identifying the barriers against improved compliance during the primary care stay.

1.4.3 Assessment of Compliance

A number of methods are available to assess the level of compliance. Measuring adherence adequately offers numerous challenges. Patient self-report, physician assessment, and tablet count are commonly used because of their practicality and low cost. Drug levels in the serum or urine can be used to estimate drug-taking behaviour, but are invasive and expensive techniques. All of these methods monitor adherence sporadically and have their advantages and disadvantages, none of which is perfect and applicable in all situations. These methods are briefly discussed below.

Tablet Count

This technique will be discussed in more detail in Chapter 2.

Blood and Urine Level Monitoring

This method depends on direct assay (whenever possible) of a drug or one of its metabolites in blood or urine to estimate compliance. Drug concentration in the urine would only indicate whether or not the drug was taken within a certain time span depending on that drug's half-life. The absence of the traces of drugs with long half-life (*e.g.*, Chlopropamide) in the urine gives a good indication of non-compliance (Goodyer, 2002). Results from serial blood tests once the drug has reached a steady state may also be useful.

The main three drawbacks for this method are:

1. Difficulties in arranging accurate assays for drugs to be assessed.
2. Difficulties in applying this method to medication with short half-lives. Steady state is achieved relatively quickly, so medication taken just a day or so prior to the visit may indicate adequate compliance.
3. It is an invasive procedure and patients must give permission for blood tests.

To overcome the first two problems the following method was devised.

Tracer Methods

One method of overcoming some of the problems encountered with the tablet count technique (will be discussed in chapter 2) is to ask patients to take another tablet containing a

small amount of a pharmacological tracer such as a low dose of Phenobarbitone (LDP) which can be detected and measured in blood samples. This technique was investigated by Puller *et al.* (1989), who coined the term "pharmacologic indicator" rather than simply "marker". The Pullar study was one of the most interesting studies using the LDP technique and comparing it with the tablet count technique. Using a tablet count, compliance of 90-100% was found in 75% of the patients, but 32% of these patients had plasma Phenobarbitone levels which suggested less than 90% compliance.

Phenobarbitone has a long half-life, and can determine compliance over the previous weeks rather than just days. Another advantage is that it shows relatively little inter and intra-individual pharmacokinetic variations. The dose normally used (1-2mg) does not appear to affect the central nervous system or cause any enzyme induction. However, the main disadvantage of such technique is that, either the patients have to take separate capsules of LDP, or special dose-forms incorporating LDP which have to be prepared specially for that purpose. Another weakness is that the blood samples must be taken which make it an invasive technique and may not be appreciated by many patients (Pearson, 1982).

Electronic Recording

A useful method for detecting lapses in compliance over a period of time is the use of electronic recording devices in the form of a medicine container incorporating a device for recording each time the container is opened. This may be either in the form of sensors concealed in a childproof cap (Cramer *et al.*, 1989) or hidden in a specially designed box (Cheung *et al.*, 1988a). The first devices were bulky and inconvenient to use, and because of the obvious difference in shape and size between them and the standard medicine containers they were unlikely to reproduce the natural setting, as it was difficult to carry or use in a flexible manner and to reflect the normal medication-taking behaviour (Rudd *et al.*, 1981). This was followed by the "medication compliance monitor", which consisted of two blister packs and a microprocessor in a plastic case (18cm X 6cm X 4cm). The limitations of this device included its big size and the 20 minutes needed to set it up and fill. A slightly smaller device (11cm X 9cm X 3.5cm) was developed, which can measure the number of openings in any hour (Cheung *et al.*, 1988b).

Finally, a device was produced which mimicked a normal container more closely. The "medication event monitor system (MEMS)" consisted of a standard container topped with a cap containing a microprocessor, which recorded each opening. Data can be retrieved by connecting the cap to a personal computer that reads the data from the tablet caps' microprocessor and generates a printout of the patient's recent bottle opening pattern (Rosen *et al.*, 2004). Detailed reports of each dose event, intervals between the dose and the percentage of days when the correct number of doses are taken can all be produced. Medication monitors can be considered as the only method of measuring compliance that allows accurate assessment of the timing of doses. An obvious disadvantage is that the dose is not necessarily removed each time the bottle is opened *i.e.*, patients may choose to open the containers without consuming any medication, so one cannot determine if and when medication is ingested. Also, multiple doses may be taken from one bottle opening *i.e.*, morning and evening doses can be taken during the morning opening and electronic tablet caps will only record one dose taken (Rosen *et al.*, 2004).

Another drawback of this technique is that their use may interfere with the usual habits of patients who carry their medication with them because the caps are bulkier than small containers patients might normally use when carrying medication away from home (Rosen *et al.*, 2004). Other problems related to patients' behaviour, like swapping the bottle caps or leaving the cap off altogether can interfere with collecting data. The device is expensive and is slightly different in appearance from a normal cap, meaning that patients need to be informed about it (Raynor, 1992).

Despite all these limitations, electronically measured adherence has been more highly associated with clinical outcomes than self-report (Liu *et al.*, 2001) and pill counts (Namkoong *et al.*, 1999), suggesting that electronic data more accurately reflects actual doses taken than the other alternative techniques.

Compliance with antiepileptic therapy has been assessed by Cramer *et al.* (1990) using such a monitor and results indicated that the tablet count technique overestimates compliance; also serum concentrations do not reflect the true compliance rate. There is also electronic device

for use with an inhaler which records when an actuation has been made called the Nebuhaler Chronolog (Specter and Mawhinney, 1991).

Patient Interview

A very simple and convenient method of assessing compliance is by interviewing patients; simply asking the patients verbally (face-to-face interview) or by questionnaire if they have taken their medicines as prescribed. The questions should be phrased and asked in a non-threatening or embarrassing manner which can give some indication of the medication-taking behaviour. Generally, patients over-estimate their own compliance; those who are not adhering to the regimen are less likely to admit their poor compliance, but those who admitted to non-compliance tended to be telling the truth. It was suggested that a combined method of table count, interview and prescription record monitoring would give the most accurate indication of compliance. Col *et al.*, (1990) found that 77% of elderly patients described themselves as good compliers, but when their compliance was measures using prescription records it was found that 20% of the cases were poor compliers. Lee *et al.* (1996) also reported that patients and physicians often overestimate patient adherence.

In one study by McElnay (1997), compliance with prescribed medication was assessed in a group of 512 elderly patients just before their hospital admissions. Using the self-reported technique was used to assess patient compliance. It was shown in this study that self-reporting of compliance is generally overestimated by patients. These results supported the results shown by Col *et al.* (1990) where 315 elderly patients were interviewed to determine their history of non-compliance in a non-judgmental way. Since determination of patient compliance relied on self-admission, it was subjected to underreporting because of errors in recall and the patient's desire not to uncover incriminating information.

Prescription Refills

This method estimates compliance by monitoring prescription records to see if a repeat prescription is requested for at the appropriate time. The method depends on using the pharmacy computer systems to match up medicines prescribed to medicines actually collected. In practice, it is possible to use records to find out if patients collect their monthly

repeat prescriptions. The main disadvantage of this method is that the patient may use more than one pharmacy; however, many patients prescribed medication for chronic conditions will use the same pharmacy.

Practically speaking, it is difficult to match the prescription issued from the GP surgery or hospital with those presented for an individual patient, although electronic prescribing and repeat prescribing schemes may change this situation (Steiner and Prochazka, 1997).

Grymonpre *et al.* (1998) adopted four methods to assess non-adherence in 135 elderly patients who were 65 years and over and were on one or more prescription-only medicines (POM). These were tablet counts, self-reporting interviews, reviewing manual databases available from the community pharmacies and the electronic data of POM details and dispensed medicines. The mean adherence calculated from the tablet counts (74%) was significantly lower than that calculated from the electronic databases (94.6%) or self-report (95.8%), and from the manual database (107.6%). Researchers were unable to determine which method managed to provide the most accurate estimate of adherence which may lead to the conclusion that a gold standard to measure adherence to medication does not exist and that the best method depends on the aim of the study and purpose of the data to be analyzed. Only adherence calculated from the tablet counts and electronic databases were significantly different. It can be concluded from this study that patient's self-reporting can be a useful tool in assessing patient's non-adherence which is one type of the MRPs. The drawback of patients self-reporting and interviewing them at their homes is the inability to visit and interview large number of patients *i.e.,* limited sample size of the study subjects and the time and the expenses to achieve these interviews including the traveling times and costs.

It can be concluded that there is no one standard method that can be used to measure compliance in all situations. Different techniques are available to achieve this task: tablet count; patient interview; blood or urine level monitoring; tracer method; prescription refill rate and electronic monitor technique. In the present study, tablet counts will be employed to quantify patient's adherence to their medication. Details of this technique will be discussed in chapter two.

1.4.4 Methods of Improving Compliance

A plethora of research has been conducted to measure compliance and suggesting techniques to improve medication-taking behaviour. No simple solution exists to solve this very complex issue but enough practical knowledge has evolved to provide strategies that can improve compliance in the elderly. These include aspects of two approaches to promote medication compliance: educational and behavioural. Patients can be offered appropriate information about their medicines, their regimen simplified and the medication packaging individualized to their particular needs. Compliance improving strategies will be discussed in this section.

Simplification of the Regimen

The patient medication regimen should be as simple as possible. Simplification of the regimen to once- or twice-daily medication can improve adherence. The use of longer-acting or modified-release medication may be more appropriate to improve patient's compliance, but the possibilities of accumulation of those drugs with longer half-lives in the elderly must be considered (Herrier, 1995).

For many drugs, single daily dosing will provide therapeutic effects comparable to multi-daily dosing and even with better adherence, fewer side effects, and maybe less cost. The medication compliance of 105 patients receiving antihypertensive medications was monitored from special pill containers that electronically record the date and time of medication removal. Compliance improved from 59% on a three times daily regimen to 83.6% on a once-daily regimen (Eisen *et al.*, 1990). These results confirmed the results observed in a an earlier study carried out by Jacobs *et al.* (1988) where compliance, defined as patients who consumed three quarters of the prescribed nonsteroidal anti-inflammatory agents given once-daily, was 65% while compliance for four times a day regimens was only 37%.

Many pharmaceutical manufacturers are beginning to package medication in convenient "calendar packages" to facilitate patient adherence. Another practice that should be considered to decrease confusions over medication is to prescribe the same brand of drug

consistently. Patients may get confused if they are dispensed a generic of different appearance each month.

Patient Education and Counselling

There has been much debate concerning the effect of patient knowledge on adherence to their medication regimen. Whether or not knowledge of medication can actually improve adherence, patients should be in possession of the necessary information if they are to take an active role in the discussion regarding their therapy. Educating patients about their diseases may not affect treatment compliance, but time devoted to educating patients about their treatment regimen may improve adherence (Stewart and Caranasos, 1989). Continual introduction of more complex medicines has increased the need for patients to receive more information on the way of using these medicines (Hayes and Livingstone, 1990). Correct, simple, clear and concise instructions, particularly if they are repeated at regular intervals, with a clear explanation of the need for therapy and questions concerning adherence to the treatment regimen, can generally improve adherence. Also, the fewer the number of instructions provided, the greater the chance that they will remember and recall. However, this is not an invitation for giving less information. Patients are more likely to remember items at the beginning and end of explanation than those described in the middle of a session (Kitching and Jones, 1990). Instructions that are stressed to the patients are also better remembered (Stewart and Caranasos, 1989). It is strongly suggested that an incremental approach to patient education is the most effective technique and results in the desired long-term benefit (Herrier, 1995).

Much literature described the influence of 'counselling' by different healthcare professionals (prescribers, pharmacists, nurses or any other healthcare professionals). True counselling service can be defined as "*giving advice so that the patients may make their own decisions*" or as "*the provision of information on medications and related health issues*" (Aslanpour and Smith *et al.*, 1997). Hayes and Livingstone (1990) suggested another definition for counselling in the community as "*any verbal information relevant to the prescribed medicine given to the patient by the pharmacist or an assistant*" and the process of patient education can be defined as "*those communicative activities which have the objective of supporting*

patients' drug therapy decisions" (Blom *et al.*, 1998). None of these definitions really described a counselling service in the true site of the ward, where the patients can explore their own feelings and beliefs. What seems to be offered in most descriptions of medication counselling is actually an education service, where the patient is also invited to comment on issues regarding difficulties associated with poor compliance, *e.g.*, inability to take medication and adverse effects. It is within this remit that medication counselling is referred to in this thesis.

There are two contexts in which patient education concerning medication-taking is performed; in the secondary care after dispensing prescription through outpatients or prior to hospital discharge at the patient bedside. Community Pharmacies also provide information on dispensing prescription or on selling OTCs. In both the primary and the secondary care settings, pharmacists, doctors and nurses may all be involved in providing information and monitoring the appropriateness of medication. Patients who are recently discharged from hospital may reasonably be expected to use their medicines most effectively if they are given information about the purpose of medication treatment and the anticipated benefits or problems. Patients discharged from hospitals should be able to manage their medication supplies correctly; they need to be provided with information and advice about the intended duration of treatment, how to maintain a regular supply of their medication, the best way to store these medicines and how to dispose of unwanted medication. There is a general agreement that patient education programmes aim to provide this type of information to promote better adherence (Cantrill and Clark, 1992).

The provision of verbal advice on prescription medication is an accepted part of the pharmacist's role. The way the information is presented, both written and verbally, is very important. Proper communication skills between the patient and the information provider are required which allow better understanding by the patient (Kitching and Jones, 1990). The oral information and written instruction should be of the quality and the quantity that the patient needs, not necessarily those dictated by the manufacturer or what the prescriber prefers. Patient should be also given an explanation about any medication which is

discontinued or newly started (Cantrill and Clark, 1992). To enable patients to attain better adherence they need to understand the importance of adherence (Astrom *et al.*, 2000).

Any education programme aims to provide information of a reasonable structure and quantity that the patient is able to understand, digest and apply. Although written materials may be useful, effective oral communication is one of the most important aspects of patient education because it directly involves the patient and the health care professional in a two-way interaction; patient by asking questions and the health care professional by negotiating the treatment and checking their understanding (Anderson, 1987).

It has also been found that the benefits of treatment in hospital may be lost if inadequate information is given to patients, carers or professionals. Patients, who do not follow the provided instructions or take their medications in the most appropriate way, have higher morbidity levels which may need more medication and longer and more frequent hospitalization (Milliken and Rea, 1997).

In a study carried out by Lowe *et al.*, (2000b), 161 elderly patients, taking three or more medications were recruited to study their behavioural pattern towards their medications and to determine the effect of an education programme on patient compliance. Intervention patients were informed about the proper a use and purpose of their medication regimen. The information was then summarized on a handwritten drug reminder chart. Patients' adherence to their medication was assessed using the tablet count technique. The mean compliance score for the intervention patients was 91.3% compared to 79.5% in the control patients who did not receive any medication counselling sessions. The study showed that combining medication review with deep patient education in the community can significantly improve patient knowledge of and their compliance with medication in the short-term and maximize the benefits patients gain from their medication. The main weakness in this study was the use of non-blind assessment, as the same person carried out both the intervention and the assessment.

There are many factors affecting patient's recall to the medication information, the way the information is presented to the patient and the active participation of the patient in the discussion with the health care professionals. Another factor is the terminology; health care professionals may use unfamiliar technical terms which are not suitable for most non-medical people. Since an understanding of words in a message needs the patient to process, learn and subsequently recall instruction, it is acceptable to assume a pharmacist's vocabulary will affect study outcomes. Cochrane, (1992b) explained this with the following example, telling a patient that "*alcohol ingestion superimposed upon inadequate dietary intake can precipitate acute hypoglycaemia*", is more unlikely to be understood and to improve patient's ability to recall than: "*Do not drink beer, wine, or other alcohol on an empty stomach*". The other factor which should be considered and may affect patient's ability to recall is the specific and "action-oriented" phrases which are more likely to be remembered by the patient than the general ones. Other factors are: the way the information is organized (including which instructions are given first); the location where the instructions are given (hospital, surgery, community pharmacy or patient's home); the level of patient's anxiety; the use of repetition, and the interest the pharmacist shows in a patient (Cochran, 1992b).

This method of improving patients' compliance to their medication will be discussed in more depth in Chapter 2 as it will be adopted in this project as one of the steps in enhancing patient's discharge from the hospital.

Compliance Devices

There are many types of devices that are easy to use and are claimed to help patients remember to take medication especially for patients with compliance problems who have failed to respond to multiple interventions, or who have specific problems related to medication taking (Sprey, 1995). For the patients to benefit from these devices they need proper instructions and support in their correct use. The ideal device would have the following properties:

- Portable and easy to open and use.
- Safe and child-resistant.

- Does not require regular refilling.
- Can maintain the integrity of the medication.

The Multi-Compartment Compliance Aids (MCAs) are the most commonly used for patients recognized as having problems with taking medicines at home (Sprey, 1995). The aids hold seven days of a patient's medicines in 28 inner compartments, four for each day (such as Dossett and Medidos). These systems allow some degree of compliance monitoring by checking any tablets remaining in the system when returned to the pharmacy for refilling.

Other medication reminders are Compliapack or domiciliary pack, Medipalnner, Mediwheel, medsystem, Nomad controlled-dosage system for home use and Venalink (Sprey, 1995). Few can meet the specification of the ideal device and a device suiting one individual may not be appropriate for another (Walker *et al.*, 1990).

No difference was found in the number of errors made by elderly women on a rehabilitation unit who were given Dossett boxes and those who used standard tablet bottles. This may be attributed to the difficulties elderly may have to manipulate them, which may cause further confusion (Crome *et al.*, 1980). On the other hand, the opposite result was reported by Ascione and Shimp (1984). The investigator found that interventions involving the medication reminder package (seven compartment plastic package known as the Seven Day Pill Reminder) were statistically better than the other two interventions that focused primarily on providing information as oral instructions alone or with written handouts.

Cards and Calendars

It may be useful sometimes to supply the patients with a "reminder card" which is a clear written list of their medication, the names, the appearance and the dosage intended to be taken. Well designed reminder charts help with factors associated with poor compliance to drug regimens. They overcome forgetfulness by linking times for medicines to be taken with daily events to which most patients can relate *i.e.*, they overcome problems arising from vague instructions on the timing of doses, such as "three times a day", by giving specific times for medicines to be taken, *e.g.*, breakfast, lunch and dinner time. In addition, they can

prevent the confusion on deciding which medicine to take that arises when many different medicines are prescribed *i.e.,* relating the doses of each medicine to the others (Raynor, 1992). The information should include the names of medicines, the reasons for prescribing them, when they should be administered, any special instructions *e.g.,* "after meals" and the most common side effects that may require immediate physician contact (Stewart and Caranasos, 1989).

A study carried out by Raynor *et al.* (1993) using individualized reminder charts, which listed each person's medicines and when they were to be taken, showed a significantly increased proportion of patients who correctly answered questions about their drug regimen.

Patient Information Leaflets (PILs) are a useful backup to oral instructions. There is a perception that leaflets would improve patient's knowledge and understanding of prescribed medication, also they would help patients to remember what they have been advised verbally by health care professionals. In addition, these leaflets may be particularly useful to certain groups of people, *e.g.,* those with hearing problems (Thompson and Stewart, 2001a). PILs should be carefully designed to be easily read and understood by the patient, the inclusion of simple diagrams being particularly useful when a method of administration (*e.g.,* drops, suppositories or inhalers) is to be explained (Bailie and Bennett, 1987). However, they are thought to be a two-edged sword (George, 1987), as too much knowledge regarding medicines may be considered as a source of worries regarding side effects. There was also concern that leaflets may create confusion if conflicting messages were delivered by health care professionals (Thompson and Stewart, 2001a). In one study, only 15% of 200 patients, who were asked about the patient information leaflet, said that if they were to receive a prescribed medication they had to use for the first time, a leaflet about that medication would be "very helpful". A further 15% were with the opinion that a leaflet would be "unhelpful" to them personally (Thompson and Stewart, 2001a).

Tailor the Regimen to Patient Lifestyle and Routine

Most patients adopt certain strategies to help them remember to take their medication. A daily routine for taking medication should be developed that remains consistent. The

treatment pattern to be employed should be fully discussed with the patient, giving priority to the strategies which best fits their lifestyles *e.g.*, making coffee early in the morning, mailing letters at noon, or making phone calls in the evening, so taking medications could be "built into" these activities (Stewart and Caranasos, 1989). In a study by Wallsten *et al.* (1995) it was found that most of elderly patients linked tablet-taking behaviour to specific daily activities involved in their every day routine.

Weak memory is a two-sided problem, on the one hand, the patient can forget to take their medications, and the other is the patients may forget if they have actually taken them. In such cases, the pharmacist can cooperate with the patient to find a method to remind them if doses have been taken, *e.g.*, laying the medication bottle on its side after taking the dose (Herrier, 1995).

Actively Involve Patients in Treatment Planning, Monitoring and Implementation

Patients should be given the responsibility for taking their medication appropriately. Patients must be able to understand important information concerning the benefits and adverse responses they experience with their medication, as well as their particular medication preferences (Stewart and Caranasos, 1989).

The first line methods of ensuring good compliance involve measures to be taken by the prescriber. Theoretically, if the patient wishes to accept less treatment and clearly understands the potential therapeutic consequences, then the treatment should be discussed with the patient rather than being dictated by the prescriber. Involving patients in all the aspects of their care strategy increases patient satisfaction and compliance with their regimens (Becker, 1985). Also, giving the patient the opportunity to be involved in the choice of their treatment is rapidly becoming the preferred approach of concordance. Involving patients in the process of measuring their blood pressure or their blood glucose level may also improve drug therapy compliance (Eraker *et al.*, 1984).

Packages and Labels

Some specific measures regarding the elderly are advised to enhance patient's adherence. Labels are an important source of information about how to use prescribed medication. For the elderly it is often been stressed on the importance of large labels with clear instructions, using normal non-child proof containers (Thompson and Stewart, 2001a). Blister packs do offer a useful alternative to the child-resistant containers which are manageable by most elderly people.

The advantages of large labels are obvious, especially for those with poor eyesight. A review by Salzman (1995) showed that up to 60% of elderly patients experienced problems reading labels. Many respondents in Thompson's study (2001a) commented on the difficulties older people may have in reading labels because of the clarity of the labels and font size.

Having discussed methods of improving compliance, it can be concluded that patient compliance with prescribed medication directions has been a growing concern. Elderly patients are thought to have more difficulties following instructions because they generally have more medication prescribed, often suffer from cognitive decline, and frequently have physical limitations such as failing eyesight and hearing. The above discussion suggests that the following measures should greatly improve response to drug therapy and decrease adverse reactions: providing clear adequate verbal and written instructions; simplifying the drug regimen to once a day administration; good clear label, ensuring that the patient can open the container and administer the medication, provision of leaflets and special containers.

1.5 Medication Discharge Planning

This is on of the largest section in the chapter as it relates to the central theme of the thesis. The concept of "*pharmacy discharge*" has been suggested for describing the pharmaceutical services provided when patients leave hospital to return to the care of their general practitioners (Jackson *et al.*, 1993). Within a pharmacy discharge, all the pharmaceutical needs of the patient, including information are delivered in a safe and effective manner. Patient discharge tends to be seen as the termination of hospital care process and the transfer of responsibility to the patients themselves, a carer or the general practitioner. Houghton and co-workers (1996) defined good patient discharge as: *"Patient satisfaction with involvement in the process of discharge, the absence of problems after discharge, and the assessment, documentation, and meeting of needs for community care after discharge"*. The decision to discharge a patient from the hospital is usually made during a ward round for a number of reasons, not least the patient's eagerness to get home. It has been recognized since the 1970s, as discussed below that, there are a number of problems associated with patient medication after discharge from hospital. First, there are a range of potential problems when communicating the changes to medication, referred to as interface issues:

- Failure to discontinue medication.
- Failure to change the regimen of medication to be continued.
- Failure to record new medication.

The Royal Pharmaceutical Society stated that *"adequate communication between community and hospital pharmacists will ensure uninterrupted pharmaceutical care management"* (Cook, 1995). Normally, during the hospital stay patients have a number of changes made to their drug regimes. These changes may lead to MRPs after the hospital discharge because of confusion over what has been stopped, started or changed and this in turn may lead to duplication of medicines or discontinuation of newly prescribed medicines (Cantrill and Clark, 1992). In some cases, there is simply a delay in the information reaching the GP before discharge medication runs out.

Secondly, there are a number of problems that have been identified relating to patients understanding of their drugs and regimens, potentially affecting compliance. The interface

and patient factors are probably not unrelated in that good patient understanding may allow them to be better involved in their regimen and perhaps help preventing problems such as repeating old medication that they have been told has been discontinued.

The first section below considers studies that have attempted to quantify the problems associated with medication and discharge. The second section considers studies where some intervention strategies have been introduced and assessed to overcome the problems of discharge medication. Many of the studies describe a 'counselling service' provided by pharmacists just before discharge and this has been briefly described in section 1.4.4 as a potential strategy to improve patient adherence and knowledge of medicines. Typically, a medication counselling session will involve discussing with the patients their regimen, checking understanding, and discussing other particular issues that may relate to poor adherence to medication. Often, a checklist is employed during the session, for instance a very comprehensive discharge checklist has been described by Coombes and Horne (1994). This covers the following areas:

- Review drug regimen: Are medications prescribed essential? Does the regimen suit the patient's routine? Would a memory aid help?
- Packaging and supply: Can the patient obtain further supply? Can the patient open lids, pull out foil tablets etc.?
- Information: Improve knowledge of medication regimen, side effects, purpose. Use verbal and written information.
- Liaison: Carers, GPs, community pharmacists and other healthcare professionals.

This checklist was designed for use in the elderly, but others have been investigated such lists for more specific patient groups *e.g.* for patients discharge from a medical/gastroenterology ward as developed by Cantrill and Clarke (1992). The session typically lasted 15-20 minutes. Such a service is usually well received by patients and hospital staff as described in a study by Milliken and Rea (1997), but staff time commitments may limit the service. There are probably few hospitals in the UK that involve pharmacists in discharge services as an

extension of routine counselling sessions from clinical pharmacists, as was found in a survey in one region (Brown and Brown, 1997).

Most of the studies described below were undertaken on the elderly where medication discharge is of greatest importance in terms of the range of medications prescribed. They are described and analysed in some depth, being the basis for comparison in the discussion in Chapter 6.

1.5.1 Non-intervention Studies Concerning Discharge Medication Issues

There are a few non-intervention studies that attempted to quantify medication issues regarding the discharge process. Foremost in such problems is the communication of intended hospital discharge medication to the GP and of equal importance is that the patient's record is amended accordingly.

A study by Cochrane *et al.*, (1992a) investigated the difference between the discharge medication prescribed by the hospital and that being taken by the patients 10-14 days after discharge. This was assessed by visiting the patients in their own homes and noting any variation between what the patient was taking and that prescribed at discharge. The patients were questioned in some depth regarding their reasons for taking medication. One obvious deficiency in this study is that no reference was made to GP notes concerning the patient, making it difficult to identify the cause of the problems or verify if changes had been intended. Of the 50 patients surveyed 45 had some form of variation to the medication prescribed on discharge. In many cases the variations were quite superficial, for instance 25 drug names were changed from generic to proprietary and most of the dose changes were in timings not having a large clinical impact. There were 29 new drugs started but it is unclear whether there were intended new drugs from the prescriber or simply drugs that should have been discontinued. The reason for this confusion is that in 20 of these cases the hospital was not aware that patients were taking the medication before admission, so patients simply continued taking the same medication on returning home. It could not be ascertained whether such medication would have been discontinued during admission and it represents another type of interface issue. Overall, it appears that only three drugs were discontinued but the

patients used old stocks on returning home. Although the study did highlight the range of problems, it did not clearly quantify the errors on the part of the GP to act on information received from the hospital. Although in this pilot study the researcher did not describe any form of interventions that could be performed and the study was conducted on small sample size, it managed to identify cases of deviation of the prescribed regimen following hospital discharge. The results would suggest the importance of patient follow-up and good communication with GPs and community pharmacists.

The problems associated with medication post discharge have been investigated since the 1970s. Parkin *et al.* (1976) conducted a survey of 130 patients discharged from a single hospital. Even though described as elderly, the mean age of the patients was just 66 years, reflecting the change in age profile in the last 30 years. Patients were interviewed at home 10-14 days after discharge, knowledge of regimen was assessed and compliance measured by tablet count. The study categorized patients as making errors in the regimen due to non-comprehension if they reported to the interviewer an incorrect description of the regimen. However, if this was assessed without allowing patients to read their labels, as it appears from the methodology, it is possible that an overestimate of deviation from the regimen could be made. Sixty five percent of the patients did correctly describe their regimen. Compliance is reported as being below the 85% level for 25% of patients, in the region found in many subsequent studies. The researcher did not include in the estimate of compliance those with an apparently incorrect understanding of the regimen, though the reasons for this are not explained. Although the GP offered information on the intended changes they made to the hospital regimen, there was no attempt to investigate the interface issues and this may not have been perceived widely as a problem at that time. The paper reported that patients did tend to hoard medicines and revert to old drugs on discharge, but this problem was not quantified.

The majority of studies on medication discharge tend to focus on the elderly. The study by Eagleton *et al.* (1993) concerned a wide range of patients between 15 and 75 years of age and reported on medication knowledge and compliance in 50 patients visited at home 12 days after discharge. The findings were similar to those found by others in an elderly population;

the mean compliance rate was 86% with 78% showing a compliance rate of greater than 85%. More than 85% knew the details of the drug regimen, but only 10% knew the purpose and 18% the name of all medicines. Also only 30% could describe a single side effect associated with any of there medicines.

A recent national survey by Sexton *et al.* (2000) aimed at identifying the services that hospital pharmacies were providing to contribute to seamless care during hospital discharge. To achieve this aim a postal questionnaire was designed containing both closed and open questions addressed to chief pharmacists in UK trust hospitals. Information was collected regarding hospital demographic data and the manner in which discharge prescriptions are generated and checked, pharmaceutical services provided at and after discharge and the manner in which the Trusts communicate with the GPs and the community pharmacists regarding the medication regimen. Sexton *et al.* (2000) summarized some of the problems preventing the smooth transfer of pharmaceutical care, which were reported in different studies at or after the hospital discharge:

- Unexplained discrepancies between the medications prescribed on the take home prescription and the in-patient prescription chart.
- Difference between the post discharge formal letter and the prescription the patients should be taking home and deviation between the prescribed drug regimen at discharge and those prescribed by GPs after discharge.
- Lack of communication with the GPs and late arrival of information to the surgeries.
- Inabilities of the GPs to systematically visit patients at high risk after discharge, possibly due to their inadequate notification by hospitals.
- Failure of GPs or their staff to act on information they receive from hospitals.
- Disagreement between hospital and community prescribers about the exact drug regimen that a patient is meant to be following.
- Failure to inform GPs of the reasons behind the changes made in drug regimen.
- Insufficient quantities prescribed and dispensed by hospital on discharge to allow time to obtain further supplies from GPs.
- Unavailability of hospital prescribed medication in community.

- Errors in prescribing resulting from errors in transcription from discharge correspondence.
- Illegibility of discharge correspondence.

Possible limitations in terms of accuracy of the findings are that the pharmacists were asked to make subjective assessments of the extent of these issues rather than being based on any form of audit. The chief pharmacist was asked to pass on the questionnaire to the most appropriate pharmacists and so the type and seniority of the responders was not known. The conclusion to be drawn is that from the perspective of the hospital pharmacist there were a considerable number of problem areas relating to discharge medication in the year 2000.

A study in Hampshire (Brown and Brown, 1997) about the existing oral and written communication channels between the primary and the secondary care pharmacists. Ten hospital pharmacists and 90 community pharmacists were interviewed using structured interviews. Results indicated that communication between primary and secondary care occurred infrequently. Both community and hospital pharmacists were aware of the importance of preventing problems at the primary/secondary care interface, but they were unable to put into practice the strategies that could ensure this outcome. There were a few findings of particular interest. The hospital pharmacists appeared to have comparatively little regular contact with community pharmacists, but identified important potential roles for them such checking patient's medication prior to a planned admission. The community pharmacists felt the letter to the GP was the most important item of information and stated that the patient's copy was useful to them in identifying interface issues. They also put a great deal of emphasis on counselling by hospital pharmacists pre-discharge, but this was not routinely undertaken in the hospital surveyed. The community pharmacists could identify a number of examples where medication discharge issues had arisen of the type documented in other studies involving poor communication such as information on GP records and running out of discharge medicine. They also felt that the GP systems were more accurate than PMRs, though it is unlikely that they were fully familiar with the accuracy of GP records. Over 75% stated that they would like to be more pro-active regarding checking medication before admission and monitoring those recently discharged. However, it is doubtful that they

would routinely undertake such a role in addition to their usual duties, unless part of a contracted service.

The need for discharge counselling was illustrated by Cantrill and Clark (1992) where provision of this service to 60 patients was assessed in terms of problems identified at the time of the counselling session. This was provided to patients discharged from one rheumatology and one gastroenterology ward. The most common problem identified was lack of information concerning medication in 40% of patients. Other areas were inaccurate prescriptions for 12 patients and problems in administration. The authors noted that pharmacists should maintain patient contact throughout the hospital stay, not just at discharge.

An audit by Coleman *et al.* (2001) attempted to quantify the discrepancies between discharge advice notes and the GP records. In this study a hospital-based pharmacist audited the discrepancies in 6 medical practices involving 232 patients. The data presented relates to discrepancies rather than problems with prescriptions issued. It is possible that some of the problems would have been resolved before the patient received a prescription after discharge. Overall, 11 % of the discharge advice notes lacked some information that would have been important to the prescriber. This was the most frequent due to absence of dosing details and course length. From the GP notes 12% of discrepancies were caused by errors in transcribing information from the advice note into the records. The most frequent errors were duplication of drug class, changes not implemented and old medications not discontinued. The failure to stop medication in just 8 patients may be an underestimation as information regarding cessation was often not mentioned in the advice note, hospital doctors just tending to use the letters as an instruction to supply rather than a full list of intended therapy. It is also unclear whether the same patients were involved in problems with transcription as well as incomplete advice notes, making an overall estimate of problems difficult. The study seems to suggest a medication communication problem of some form in around 15% of discharge patients.

A study by Burns *et al.* (1992) quantified the discrepancies at discharge through a direct examination of prescriptions issued by the GP. They noted that the 56 patients in the study

should have received a total of 128 prescription items from their GPs if this was simply a repeat of the hospital discharge medication. Of the total GP prescribed medicine 11% of drugs were new additions and 13% were omitted on the original list of 128. The authors admitted that they could not state with certainty whether omissions were intentional. This illustrated the difficulty of clearly quantifying the range of interface issues involved in medication discharge. Also, having more than one investigator assessing the different outcomes post hospital discharge, may introduce an extra source of bias affecting the results due to variation in the experience of the different investigators. A useful study might be to track prescriptions discrepancies back to the GP to see if an intended change had occurred and also to the hospital to identify if they were aware of certain medications being prescribed prior to admission.

1.5.2 Intervention Studies Involving Pharmacist Pre-discharge Counselling

There appear to be four important interventions that have been investigated concerning medication discharge planning:

- Counselling of patients immediately pre-discharge.
- Follow-up and counselling post discharge.
- Provision of patient reminders and information cards.
- Information letters to GPs and/or community pharmacists.

Not included in this review are those studies from outside of the UK. The unique nature of the NHS often makes it quite difficult to draw comparisons to studies conducted in countries with different healthcare systems. For instance, the discharge process of communication between hospital and GP will be quite different. Also, the level of support offered to elderly patients in the community would vary in other countries; many would rely more on family support than the UK or US. The activities of the community pharmacist can be radically different even within the European Union and many countries have a far less clinically orientated role for pharmacists. Even though community pharmacist involvement in services such as domiciliary visiting and medicines management is not currently widespread in the UK, they will certainly become more mainstream NHS activities in the coming years and

would explain the growing number of studies in this area in the UK compared to other countries.

For convenience, the studies have been categorized according to their age. The studies should be viewed in the context of the major changes to the NHS and delivery over the last 30 years. Those pre 1990 may have less relevance to the modern NHS with its emphasis on primary care.

Post 2000

Al-Rashid *et al*, (2003) conducted a recent study bearing perhaps the closest relationship to the subject of this thesis. This involved pre-discharge counselling with two objectives; to improve knowledge of medication and encourage greater compliance. Indeed these outcome measures are almost universally applicable to the various studies described in this section. Outcome measures therefore include an assessment of medication knowledge and measuring compliance by a tablet count. The study also included an assessment of unplanned GP visits after discharge as well as rate of readmission. Altogether, 90 patients were recruited from two wards in a care of the elderly unit, counselled on the use of their medicines and then followed up at 2 weeks and three months post-discharge, where medication knowledge and compliance were assessed in the patient's home.

As the Al-Rashid *et al.* study is so similar to the present thesis it is worth considering the methodological shortcomings in some detail. There are some concerns regarding patients selection in that elderly patients were recruited if a clinical pharmacist felt that they could have problems with medication after discharge, but it is not stated what such problems might have been. This could introduce selection bias in the population studied if for instance there was a tendency to recruit patients of poorer drug knowledge into the control group, which could have been possible from the design described. The other major methodological problem, acknowledged by the authors, was that the one ward was chosen for recruiting control patients and another for those in the intervention group. It is possible that the range of medical conditions, types of medication or quality of the usual discharge procedures may differ between the two wards. The authors did not report any baseline data concerning these

points. It also appears that both control and intervention groups received medication reminder cards as well as discharge details being sent to GPs and community pharmacists. Therefore, the hypothesis was simply that a 30 minute session covering details of medication regimen, encouraging compliance and improving knowledge would impact on the outcome measures described above.

An improvement in knowledge was claimed by the authors, but the data only supported such an improvement in the area of 'drug use', whereas knowledge of regimen remained high in both groups. However, the authors did not describe the categories of knowledge within this broad heading. This theme of poor reporting of knowledge categories and scoring system was presented in a number of the studies described in this section.

In terms of compliance, there were some remarkably big differences between groups reported. The compliance measure was presented as a percent of total number of items where compliance reached 85%-100% as estimated by tablet counts. By the second visit this was 70% of items for the intervention group but just 16% for control. The results could be explained by the strict cut-off points. For instance, if the compliance level by tablet counts had been 80% in both groups at baseline and then improved by just 5% in the study group, then by the system described in this paper a false impression of the improvement would have been given. This illustrates the importance of presenting ranges of compliance, either as means with standard deviations or categorically at different levels.

The paper described the study group as involving less GP visits and fewer hospital admissions. The reasons for admission or GP visit are not described so could be unrelated to poor compliance or drug knowledge and may be due to the previously stated selection bias. The other interesting finding was that patients passed on very few of their discharge letters to the community pharmacists, but tended to do so for the GPs. Finally, as with many of these types of intervention study the assessments were not blinded.

There are a few studies that have investigated the influence of pharmaceutical care strategies initiated during hospital admission and then assessed their impact post discharge. One such

small study by Pickrell *et al.* (2001) assessed the influence of such care regarding discrepancies between medication prescribed in hospital and that prescribed by the GP. This was assessed on admission in terms of what the prescribing physician believed to be the patients' usual admission compared to that actually prescribed by the GP and whether this had been resolved at discharge. Fifteen patients were counselled both on admission and discharge and letters summarizing changes in their regimens sent to the patient's GP. Another group of 17 patients received only the standard hospital care. Of interest in the context of discharge counselling and communication with GPs is the number of discrepancies recorded at 2 weeks; 0.86 per patient in the intervention groups compared to 3.7 in the control group. However, the figures need to be considered in the context of the study limitations. This is described as a 'qualitative' study, yet is based upon reporting of only quantitative data. Group allocation was not randomised but purposive and the study is described as exploratory involving only 41 patients. The method for identifying discrepancies at follow-up was unclear as it is stated that 'prescriptions were compared' but it was not described how such prescriptions were identified or compared to GP records. The discrepancies may have been queried over the telephone interview with patients, a very inaccurate method of such an assessment.

There are not many examples of multi-centre trials involving medication discharge planning, but one major study (Nazareth *et al.*, 2001) failed to identify any benefits from the scheme it described. In this study pharmacists from four hospitals passed on detailed discharge plans to one of 29 community pharmacists who followed up patients in their own homes. This was a randomised controlled trial with the control group receiving no pharmacy visit. As well as compliance and knowledge, other outcomes such a readmission, outpatient attendance, general well being and numbers of deaths were assessed. Apart from a small improvement in patient knowledge in the intervention group no other significant differences to controls were found at two weeks, 3 months, 6 months post discharge. There are a number of important points concluded from this study:

- Although community pharmacists were given some training it is possible that this was not adequate to familiarize themselves with the clinical issues.

- The elderly patients each had a number of chronic conditions contributing to morbidity and overshadowing any of the medication-related events leading for instance to readmission and death.

- No discharge counselling was given prior to discharge and baseline was at 7-14 days. It is possible that such counselling by a hospital-based pharmacist would have prevented problems more effectively post discharge.

- The community pharmacists did make a large number of interventions regarding medication regimen, although these were mainly to provide the patient with information to dispose of unwanted medicines.

- Compliance was reported as high in both groups but the method of assessment is not described *i.e.* is usually high if just relying on self reporting. Similarly, assessment of knowledge is not discussed

The important message from this study is that, it is difficult to detect true clinical advantages from medication discharge planning and that home visits from community pharmacists in this context may have little added advantage. However, some of the secondary outcomes such as compliance, knowledge and level of intervention/potential medication-related problems were not properly investigated.

One useful way of facilitating the discharge process is to use a dedicated hospital-based liaison pharmacist and one study (Brookes *et al.*, 2000) claimed a reduced readmission rate in those receiving this service. However, the study was poorly controlled and not randomised. The claim for reduced admission was simply made by comparing the rate for those receiving the service (66 patients) to the average re-admission rates for the same age group within the entire hospital. The study also consisted of an intervention by the pharmacist on admission where a large number of MRPs were identified. A control group to compare identification of problems by a non-dedicated pharmacist is not present. Discharge information was communicated to the GP and community pharmacist by the dedicated liaison pharmacist but

any direct effects of such information was not assessed as patients were not followed up on discharge. A questionnaire sent to GPs and community pharmacists did indicate that they felt the information to be of use.

The effective transfer of information is fundamental if pharmaceutical care is to be truly seamless. It would follow that if MRPs can be reduced by such a system then potential benefits could be identified. One of the difficulties is to standardize the reporting of such problems to obtain consistent reporting in order to compare studies. It may be the case that transmitting pharmaceutical care issues is even more important when involving a medical speciality rather than the general care issues in care of the elderly, as the non-specialist GP or community pharmacist will be less familiar with the specialized drug therapeutics.

This was well illustrated in a study by Morrison *et al.* (2004), which was an uncontrolled pre and post intervention study involving discharge of patients from a specialist pediatric unit. The study involved initial focus groups of patients, GPs and community pharmacists to determine the range of pharmaceutical care issues in the patient group. The intervention consisted of the transmission of a detailed pharmaceutically related discharge letter to the GP and community pharmacist focusing on issues such as the use of unlicensed regimens, unusual doses, formulations and routes of administration. Outcomes were assessed by questionnaire sent to the GP covering satisfaction with the information received and to the community pharmacist covering types of pharmaceutical care issues and parents concerning the issues they encountered. There were 55 patients in the pre-intervention and 47 in the post intervention phase. The most interesting results were those reported by the community pharmacists, where a large reduction in pharmaceutical care issues were reported post intervention. These improvements were in those areas very much related to the speciality rather than general issues such as dosage information or reason for medication. In the main, the issues concerned simply reassuring the pharmacist that the prescription was correct *e.g.* not needing to contact the hospital to confirm an unusual regimen, rather than actually avoiding a potential clinical problem. Obviously, the pharmacist was not blinded so a very subjective view of the problem was given. Lack of a control group would question the

matching of the pre and post intervention groups and the group characteristics are not fully reported.

Studies 1990 – 2000

There are very few examples of studies that have attempted to asses the clinical importance of problems arising through discrepancies between discharge medication and that taken when the patient returns home. One small scale study by Smith *et al.* (1997) involved 53 patients, did investigate this aspect and was quite well-designed. Elderly patients were randomised into a control or counselled group, the visiting pharmacist was blinded to group allocation and a panel of clinicians judged the clinical relevance of any intervention or discrepancy identified. The design was quite simple in which all patients were visited at home 7-10 days after discharge to assess compliance by tablet count, knowledge of medication by interview and discrepancies to discharge medication. The pharmacist made interventions for both groups on any discrepancies found. The visiting pharmacist contacted the GP concerning such discrepancies and obtained further details for the panel assessment. One group of patients received medication counselling by one of a number of clinical pharmacists before discharge and also provided with a pharmaceutical care plan to pass on to their doctors or community pharmacists.

Unfortunately, reporting of results in this study is somewhat lacking and it is difficult to draw many useful conclusions. Compliance is simply reported in terms of numbers of patients where this was felt to be a MRP, no absolute levels being provided even though tablet counts were performed. Similarly, incorrect use of medication is reported without specifying any further details. In terms of compliance and drug use problems though, the counselled group did perform significantly better than controls. The total number of discrepancies where a GP was contacted totalled 31 and there was no difference between the two groups. This would suggest that the intervention did not necessarily reduce the incidence of interface issues. The panel noted that the largest number of discrepancies, 16 in total, 'restored the efficacy of discharge medications' but no details were given as to the precise meaning of this classification. All of the interventions assessed did result from unintentional continuing of pre-admission medication.

A key element to discharge planning is the transfer of accurate information to the primary care setting. Some UK studies have attempted to utilize the community pharmacist in this context by communicating to them details of discharge medication. The patient is asked to nominate the pharmacy to which the information is sent, the theory being that they are then in a position to identify discrepancies in terms of unintentional changes to the discharge medication, particularly when it reverts back to pre-admission medication unintentionally. One of the most detailed examinations of this type of system was conducted by Duggan *et al.* (1998), although not without some flaws and limitations. It is worth considering in some detail as although it did not exclusively involve older patients, the study did attempt to quantify the impact of this type of intervention. The study design was a prospective controlled trial in which patients were assigned either to an intervention group to whom community pharmacists were sent a discharge letter or controls where no letters were sent. Two weeks after discharge both groups were visited at home by an investigator who noted discrepancies between the intended hospital discharge medication and those obtained via the GP at this point.

The group allocation was not randomised and although some data was presented to indicate matching, it is not described how well they were matched concerning discharge medication. In addition, the investigator was not blind to group allocation. The discrepancies noted in the visits were then presented to a panel of hospital consultants to grade as none, possible or definite adverse effect on the patient. This exercise was conducted rigorously with a retest of the same panel one month later. As with all such studies the panel decision is limited to the information provided. In this study no reference was made to GP records and therefore no information could be provided to the panel from this source. In addition, the visiting pharmacist was required to make an assessment of 'unintentional changes' even though no check was made that this was the case from the prescriber's perspective. The authors also argued that the panel were uncertain of the classification of some potential into the definite category due to lack of information The reverse case could also be true as with more information potential or even definite changes might be downgraded as being less important. Further possible criticism are that only the actual discharge medication appears to have been transmitted to the community pharmacists without other details such as those drugs that

should be discontinued. The authors gave no information concerning the nature of the discrepancies or attempted to scale the seriousness of the adverse events. The motivation of clinical pharmacists to provide this type of service outside of the study can be questioned as no remuneration was offered.

The results from the Duggan *et al.* (1998) study identified a significantly higher level of adverse events in the control group; 1.6% definite for the intervention group compared to 3.1% in the control group as a percentage of all unintentional discrepancies. Overall, the number of discrepancies for prescribed drugs was as high as 32% for the intervention group and 52% for controls. The authors found that for every 19 patients where information was not supplied to the community pharmacist, one would have a definite unintentional adverse discrepancy. It is important to bear in mind that this is only a potential adverse effect, as adverse events where not noted within the remit of the study. In conclusion, although a very diligent study it does highlight the methodological problems in designing studies to assess this type of activity.

Another study that examined the impact of information passed between the hospital/community interface was that by Binyon (1994), where very detailed pharmaceutical care plans were sent from the hospital. This was a single cohort prospective study and also involved a high degree of patient counselling, not just on discharge but throughout the hospital stay. Just prior to discharge, care plans were sent to the GPs and community pharmacists detailing medication changes, important points of the hospital stay, packaging and labeling instructions and regimen changes. A home visit was made 1-2 weeks post hospital discharge to assess compliance by tablet count and knowledge of medication. A second home visit was made 4 weeks after discharge to assess medication changes. Forty three patients were entered into the study. The care plans only described 5 changes that should be made at a latter date by the GP and these were acted upon. Overall, there were 51 care plan points made and 23 were acted upon. However, most of these concerned issues such as providing non-childproof tops, routine biochemical tests or avoiding represcribing certain items. The community pharmacists only responded to 50% of the container changes and GPs to a similar proportion for biochemical tests. For reasons not explained in the paper

only 15 patients were visited to assess compliance and drug knowledge. Eleven had 100 % compliance and knowledge had improved in 13 patients when compared to baseline taken on admission. It is not stated how knowledge was assessed. The figures are broadly similar to other intervention studies of this type. The major limitation of this study is an absence of the control group. The recommendations made in the care plan may have been initiated independently by the GP or pharmacist and knowledge scores also improve throughout hospital stay. The authors described a number of specific cases where important information was conveyed and acted upon which may not have occurred in the absence of such information. The most interesting aspect of the study is that changes initiated by the GPs post discharge need not necessarily be unwarranted or of high importance. Of the 105 changes noted, a high proportion simply related to a less specific dosing regimen *e.g.*, labels reading once a day instead of in the morning when timing was not necessarily critical. Any name changes in medication were simply related to proprietary names and most of the regimen changes initiated did appear logical. It might be concluded from this study that very detailed pharmaceutical care plans concerning patient specific details may not be worth conveying to GPs or community pharmacists. There were some cases of patients being inappropriately reinitiated on medication discontinued by the hospital. Therefore, descriptions of discharge medication and specific instructions regarding previous medication to be discontinued may be the most important areas of information to be passed to GPs and community pharmacists.

Although not involving pharmacist in patient counselling, it is of interest to note another scheme involving a form of patient counselling throughout hospital stay through a patient self-medication programme. In this type of scheme patients administer their own medicines and are educated and given increased responsibility through their hospital stay. The study by Lowe *et al.* (1995) investigated the impact of this scheme on elderly patients in terms of drug knowledge and compliance by tablet count. The study was controlled but not randomised and the assessor may have been aware of the group allocation. A total of 88 patients were recruited and assessment was made by tablet count and home interview 10 days after discharge. The effect on compliance was similar to that seen in other pre-discharge counselling studies; 95% for the intervention group and 83% for control. The somewhat high figure for controls may be due to the fact that they were also given reminder cards.

Knowledge was only assessed in terms of patients knowing the purpose of medication; 46% correct for control and 90% correct for intervention.

The study by Begley *et al.* (1997) primarily investigated the effect of a domiciliary visiting scheme but is included in this section as elderly patients were recruited from the hospital and visited at only one or two days post hospital discharge for medication counselling. These patients were allocated to one of three groups; receiving home visits and counselling, home visits only for assessment and one which received visits only at the end of the study period at one year. Intervention patients were counselled and assessed at the first visit then re-assessed at weeks 2, 4, 12 and one year for drug knowledge, patient dexterity in administering medication, storage of medicines, contact with GP and compliance by tablet count. No details were provided regarding the scoring system employed to assess drug knowledge. It was also described that interventions regarding MRPs were made, but the results do not appear to have been reported. The group allocation was not randomised and the investigator was not blinded. The knowledge score did improve at two weeks after counselling (mean score 82%) but thereafter declined by 12% over the year to reach the same level as the control. The same picture consistent with other studies regarding mean compliance rate was reported; 78% at two weeks for control compared to 94% for the intervention group. Compliance levels held quite well at one year with 86% for the intervention group and 76% for control. This would appear to challenge the conventional view that compliance is relatively high just after discharge then declines. Also, the effect of just one counselling session has maintained compliance for a whole year. One possible explanation is that the regular visits may have maintained compliance even though no specific counselling was given. This explanation is supported by the fact that the third group only had a compliance rate of 69% at one year. Unfortunately, no baseline visit was made for the third group making it difficult to support this hypothesis. Other useful findings were a reduction in hoarded drugs and better storage of medication for the intervention group. The counselled patients appeared to have less contact with GPs, but this was only significant at 12 months. As patients were only asked directly regarding GP contact investigator bias cannot be ruled out.

Raynor *et al.* (1993) carried out a detailed investigation concerning the use of a reminder card for discharged patients that was computer generated and individualized. The 197 patients recruited were randomised into four groups; receiving brief nurse counselling, receiving brief pharmacist counselling, nurse counselling plus card and pharmacist counselling plus card. The patients were visited at home 10 days after discharge for tablet counts and testing of knowledge of their medicines. No difference was observed between the two groups who had received the reminder chart and the same for the two groups who had not received charts and these were combined for analysis. One of the most interesting aspects of this study is the efforts taken to blind patients concerning tablet counts. This was achieved by removing the tablet supply and counting them away from the patients and a later date, with the explanation that they were being taken to replace with fresh tablets. In addition, excess quantities were supplied to minimize patients adjusting numbers in the bottle just before the interview. Despite these measures results were consistent with other studies; the mean compliance was 86% in the control compared to 95% in the intervention group. This translated to 63% of patients achieving greater than 85% compliance in the control group compared to 86% in the intervention group. The 10% difference in mean compliance rate is less than the 15% found in many other studies. This is probably due to the relatively brief counselling session, although the affect of the reminder card was found to be significant using factorial analysis. Knowledge of the regimen also improved in this study; 47% correctly explained the regimen in the control group compared to 74% in the intervention group. However as with many studies of this type the investigator was not blinded.

An abstract by Horne *et al.* (1995) described a prospective controlled trial of a pharmacy-related hospital discharge programme. In this study, pharmaceutical care needs were checked prior to discharge including knowledge of medication, adherence issues, suitability of regimen and liaison with the community. It is unclear from the abstract what type of information was given to the intervention group. The interviewer was not blinded to the group allocation and made assessments both pre discharge and post hospital discharge at 2 and 8 weeks. Despite a variety of outcomes possible the authors only reported on compliance level and medication knowledge. Also, details regarding the calculations made on tablets counts were not included. At 2 and 8 weeks the intervention group reported a significantly

higher compliance level; 67% and 60% for control compared to 76% and 70% for intervention. They also reported no difference in the knowledge score at any stage, although details of the knowledge assessment and scores were not presented. If knowledge was not improved then the greater compliance rate may have resulted from some other factor in the counselling session, but the details of the session were not given. It is probably an overstatement by the authors that the benefits of pharmaceutical care are apparent 8 weeks after discharge.

Pre 1990

One of the earliest studies to examine the effects of counselling for elderly patients prior to discharge is that by MacDonald *et al.* (1977), where changes in compliance was the main outcome measured. This was a controlled trial but not randomised with consecutive patient allocated to one of three groups; 60 patients were counselled before discharge, 45 counselled and given a compliance aid and the control group patients were not counselled. No details were given regarding the type of counselling offered. Compliance was assessed and categorized in the following way:

- Under dosing as measured by tablet count on returning for an outpatient visit one and two weeks following discharge. This was categorized as taking less than half of the week's tablets medication at the visit.

- Overdosing if during a spot check at home they had taken the week's medication in four days or less.

- Consuming old stocks of medicines or other individual's tablets.

Estimation of compliance only by tablets returned is prone to inaccuracy as tablets from old stocks may have been consumed. The use of 50% compliance is not very stringent and the standard is now accepted as being below 75%. In addition, the age of the study may make it less relevant to current clinical practice. For instance, nearly a quarter of the underdosing errors related to slow release potassium therapy, which involved taking quite large numbers of tablets and this is only now rarely prescribed in clinical practice. The findings did appear

to reduce self-medication errors in the categories described, although 80% of errors had occurred in the first week. This indicates that counselling improved such factors as taking other medication or using old stocks. In general, it is difficult to compare this to latter studies due to the way in which compliance is categorized. Knowledge was assessed crudely by clinical pharmacists at 12 weeks and was classified as being good, moderate or poor. This was a subjective assessment only and no details were given regarding the questions asked. Surprisingly, a correlation was made between knowledge and compliance but it is not stated if pharmacists were blinded to group allocation. The study identified no particular advantages for using compliance aids in relation to the various outcomes. One unique feature of the study was the inclusion of patients with very low mental status scores. Even in these patients modest and statistically significant improvements in compliance were observed, though to a lesser degree compared to those with a MSQ greater than 12. The inclusion of all patients regardless of frailty or cognitive ability may mean that some were not self-medicating and were helped by carers. As the study is over 30 years old, the type of support offered in the community would be different to the present.

Another early large study to focus on the effect of pharmacist counselling pre-discharge was that conducted by Sweeney *et al.* (1989). This was of the usual design where patients (109 in total) were assigned to either a counselled or control group. The intervention group patients were counselled by a number of different clinical pharmacists and then visited at one week and six weeks post discharge by a single researcher who performed tablet counts. The findings were consistent with other similar studies at one week post discharge; 75% of patients were more than 85% compliant in the control group compared with 95% of patients in the intervention group. This level of compliance remained the same for both groups at six weeks. The other finding was a significant relationship between compliance and regimen complexity. There are two methodological aspects worth considering in this study. Firstly, it was not randomised, the control group being recruited consecutively before the counselled group. This could obviously introduce some bias into group allocation, and although apparently matched in some aspects, aspects such as mental status and clinical condition were not assessed. The reasoning for this design was that if randomised, nursing staff may influence the control group level of counselling when they were aware of the pharmacist

activity. This is a valid argument but such a phenomenon has not been assessed formally. Furthermore, it is unlikely that nurses would have routinely spent the extra 15-20 minutes on detailed medication counselling if this was not part of their allocated duties. The researchers rejected using a different ward as control as they were mixed sex wards. The other methodological aspect to consider was that a new medication stock was supplied at home visits and presumably the tablet counts performed away from the patient. It is not stated whether or not patients were aware of the tablet count process.

The study by Edwards and Pathy (1984) has been one of the few to compare the effects of discharge counselling delivered by different healthcare professionals in terms of differences in levels of compliance achieved by patients. The study appears to be well designed, being a randomised and controlled trial with patients allocated to receive counselling by a nurse, pharmacist, doctor (129 patients) or no counselling (44 patients). The counselling session was delivered on the day of discharge by a blinded healthcare worker. Knowledge was not assessed directly and no description was given concerning the range of medication prescribed or clinical conditions making it difficult to assess matching of groups. The only other criticism is that six days post discharge may be too soon to assess the longer term effects of counselling. No attempt was made to address interface issues. The results presented are consistent with many studies of this type; the control group achieved a 75% mean compliance rate at this short time after discharge compared to that in the counselled group of 90% *i.e.*, a 15% improvement. There was no difference between the outcomes for counselling by the three healthcare professionals. The authors noted that counselling did not stop the taking of drugs that should have been discontinued, but this was not quantified in any way by the results present.

Typical of a variety of small scale studies that have attempted to improve knowledge of medication prior to hospital discharge is that from Davidson and Hall (1989). In this randomised controlled study counselling by a pharmacist was given two days prior to hospital discharge and knowledge was assessed 2-3 months post discharge. The abstract did not describe whether the pharmacist assessing knowledge was blinded. Only 18 patients were recruited into each group, and those in the intervention group received counselling covering

knowledge and ability to self-administer the medication. The abstract described an improvement in total knowledge score, with the biggest improvement in knowledge of side effects and reason for taking medicine but no test of significance performed. The scores for individual aspects of knowledge were not given and the scoring system also was not described.

A small scale study to examine the effects of pharmacist discharge counselling to elderly patients was conducted by Johnston *et al.* (1986). This consisted of just 27 patients in total but was randomized, controlled and blinded with respect to patient assessment. Counselling was conducted over 15 minutes on the day of discharge by a pharmacist and the assessment of knowledge was made by a blinded psychologist. The control group received no counselling and was assessed in the same way. The researchers also took precautions to ensure that the groups were matched in terms of ability to receive information using an information/orientation scale. The paper is only a short report so very little detail was given regarding the individual scores for the categories of knowledge tested. Overall, the counselled group had far higher levels of knowledge of their medication. Apart from the small sample size, the other main weakness is that the psychologist only tested recall latter on the same day of counselling, giving little impression of medium or long-term recall.

This review does not consider studies from outside of the UK for the reasons explained above but it is worth looking at one study from Australia as a comparison. The study by Anderson (1987) consisted of the usual design involving groups of elderly patients, one of which was counselled just before discharge. The patients were visited in their own homes about one week after discharge and levels of compliance and knowledge assessed. The study did not identify a significant improvement in compliance even though there was a trend in this direction in the intervention group. This may have been an artifact of the analysis as compliance was assessed as poor (<75%), fair (75-90%) and good (90-100%). If mean compliance had been measured a different outcome may have resulted. In addition, combining groups for chi-squared analysis did show a significant difference; counselled were 90% above 75% compliance compared to control only 58% at this level. This finding for the counselled group is similar to the UK studies. Knowledge was only assessed in subjective

terms of sufficient/insufficient. The intervention group did appear to have greater knowledge. The authors did note that the main reasons for poor compliance were unpleasant side effects and discontinuation due to self-evaluated improvement in condition.

Conclusion

In summary the problem of medication discharge planning has been known and studied since the 1970s. Schemes to overcome problems have been piloted, most involving pre-discharge counselling and/or communication to the GP/community pharmacist. Most of these have some form of methodological short comings. These include:

- Non randomization or poorly controlled in a large proportion.
- Nearly all involved just one hospital site.
- Often involved relatively few patients.
- Most but not all did not blind the assessor.
- Most only examined the effects of the intervention up to two weeks post discharge.

In many cases this is probably a reflection of the poor national funding available for this type of work so that the projects were mainly funded by local trusts and hospitals from a limited perspective.

In a large number of the papers there is inadequate information or it is presented in such a way that makes it difficult to compare the results across the studies. This is particularly true of assessments of knowledge of medication where no consistent methodology is used. Also, the presentation of interface issues and medication-related problems is often difficult to compare across studies in those where this has been assessed.

Many studies examined the influence of counselling in terms of changes in compliance and drug knowledge. There seems to be a clear picture emerging regarding compliance up to two weeks after discharge as having a mean rate of 75% that can be improved by counselling to over 90%. Knowledge also improves by counselling but as described above, baseline and levels of improvement are difficult to quantify.

There are a number of areas where there is knowledge gap regarding discharge and medication:

- Although there are a large number of studies where a liaison pharmacist has visited patients post discharge to assess compliance and knowledge, there are very few studies where such a worker has offered further counselling, which would be an ideal opportunity, and then returned on a follow up visit to assess progress.

- The area concerning the broad range of medication-related problems following discharge has not been well studied. Some have examined the interface issues but few have examined the effects of interventions such as counselling on reducing the incidence. A full classification of medication-related problems and the impact on these of interventions does not seem to have been attempted in the context of discharge medication.

- No studies have attempted to examine health status or quality of life and only few considered satisfaction with information.

Very few examples of studies could be found where patients were counselled before discharge, letters sent to both GP and community pharmacist and then followed up in their own homes. Those that did follow such a system are either small scale or uncontrolled and do not describe a full range of outcomes. There were no examples where a hospital-based visiting pharmacist further counselled patients post discharge and the effects of such counselling assessed. It is the primary aim of this thesis to address these gaps in knowledge.

Summary

a. The extent of the problems of poor adherence and patient knowledge has been reviewed and various factors which influence these two areas identified. Although it is recognized that compliance and knowledge amongst the elderly can be poor, it is uncertain whether or not it is any worse than in younger patients. There are a number of special factors which may contribute to poor adherence in elderly.

b. Assessment of compliance is traditionally performed by tablet counting which has a number of disadvantages. There are many other methods that can be used to measure compliance, but none of these methods is ideal for every circumstance. A combination of two or more methods may be an ideal way to assess compliance.

c. Patient counselling appears to be the best way to improve patient's adherence in using the medicines, and for best results, the use of written information as a backup.

d. MRPs include adverse drug reactions, drug interactions, non-compliance and inappropriate prescribing. MRPs decrease the clinical effectiveness of medicines and consume NHS resources because they waste medicines and increase the NHS spend on medicines.

e. Pharmaceutical care involves the process by which a pharmacist can meet a patient's drug therapy needs and other health care professionals in designing, implementing, and monitoring therapeutic plans that will produce specific therapeutic outcomes for the patients. Pharmaceutical care is an important part of health care, and should be integrated with other elements.

f. The role of the pharmacist in the health care system is expanding from the traditional drug-oriented function to cognitive functions. A domiciliary counselling service should be one of the priorities of "care in the community" provided by the pharmacist.

The overall aim of this research study is to assess the effect of medication counselling on various outcomes including patients' knowledge, quality of life, satisfaction with the information and compliance and to identify problems concerning elderly patients discharged from hospital, and suggest possible solutions. Another aim of this study is to identify the MRPs elderly patients may suffer from after hospital discharge and suggest different interventions to overcome these MRPs. To quantify this part of the study it is proposed to develop ways of classifying these MRPs. In the following chapter the various instruments used in this study will be examined.

CHAPTER TWO

METHODS

CHAPTER TWO
METHODS

All hospitals in the UK have a policy of supplying patients with a small supply of medications on discharge. It is usual for nursing or pharmacy staff to explain and discuss the regimen with the patients, although the time spent and details discussed are variable. This study compares the outcomes of a standard medication counselling procedure at St. Thomas' Hospital, London with a full discharge counselling and follow-up system.

2.1 Aim and Objectives

The main aims and objectives of the study are given in full in Chapter 4 but briefly summarized here. The overall aim of this project is to investigate the influence of a novel discharge and follow-up scheme that could provide a smooth seamless pharmaceutical care for elderly patients across the secondary/primary care interface.

The project has the following objectives:

1. To design and implement a tool for providing structured medication counselling.

2. To examine whether structured medication discharge planning and patient counselling improves elderly patients' knowledge, adherence to medications, quality of life and satisfaction with the information provided.

3. To develop and assess methods of overcoming interface issues concerning discharge medication in terms of improved communication with GPs and community pharmacists.

4. To explore the implementation of domiciliary visit scheme by a hospital liaison worker for elderly patients post discharge.

5. To implement a scheme capable of identifying the different MRPs post hospital discharge and investigating the effect of the pharmaceutical service provided post hospital discharge on reducing these problems.

To achieve these objectives, a variety of questionnaires and instruments were adopted to conduct this project. This chapter will discuss this in some detail.

2.2 Instruments Employed in the Main Study

Questionnaires are considered the most common method of collecting subjective data either self-administered or conducted by an interviewer. The choice of the instrument depends on various factors including:

1. The target population and whether they suffer from any reading, cognitive or dexterity difficulties.

2. The length of the instrument, the longer the instrument the more time will be consumed to conduct the study and to perform the analysis.

3. Availability of simple and easily applicable scoring system or a method of weighting of the instrument.

Bowling (1995) has listed the most important criteria to be considered when selecting an instrument. These criteria include: reliability, validity, responsiveness, interpretation, alternative forms, burdens, practical experience of its use and the cultural and language adaptations. Some of these criteria will be explained in more detail in Section 2.3.3.

2.2.1 Mental Status Questionnaire

The primary aim of this study is to improve patients' awareness and their adherence to medication and to ensure that patients must therefore be capable of understanding and digesting the information provided to them. Mental impairment can be defined as "*memory impairment and loss of intellectual abilities of sufficient severity to interfere with social functioning*". Interview or observation of the patient involving an informant has been considered the most common method for assessing mental impairment (Engedal *et al.*, 1988). During the past four decades, a number of assessment scales have been developed for screening the mental capacity.

Most of the instruments currently in use to assess patient's cognitive function contain quite similar items and some may be interchangeable (Stuss *et al.,* 1996), being developed for the classical symptoms of cognitive impairment: apraxia[1], aphasia[2] and agraphia[3] (Engedal *et al.*, 1988). Dimensions usually include orientation in time, place and person, short and long-term memory, and ability to concentrate. Items reflect a different approach to the same question or a different scoring system.

Many different screening instruments can be used to assess the degree of cognitive impairment. The main problem in selecting the most appropriate tool is their multiple and coinciding measurement purposes; affective functioning, cognitive functioning, functional abilities and mental status (McDoughall 1990). Mental status and cognitive function were assessed in this study using the Mental Status Questionnaire (MSQ) before recruiting any patient. This questionnaire was selected as it was designed, developed, tested, standardized and validated to be used as a screening tool. Reliability of this scale has been assessed for its internal consistency (by calculating the Cronbach's alpha), inter-rater reliability (by calculating Cohen's coefficient of Kappa) and the validated by a logistic regression model (Engedal *et al.*,1988). The MSQ is a powerful discriminator of mental status in elderly patients and an adequate predictor of competence in simple self-care (Wilson and Brass 1973). The MSQ seems to be a suitable tool for the detection of mental failure in patients of old age, being easily administered by any clinician or researcher in different settings (office or hospital).

The test is composed of 26 questions as shown in Appendix I represent several different domains assessing memory functioning (short-term memory and long-term memory), orientation to surroundings (time, place and persons), information about current events, and serial mathematics abilities. In this study patients were assessed for their mental status by interviewing them face to face using the MSQ and any score under 20 being indicative of

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[1] Total or partial loss of the ability to perform coordinated movements or manipulate objects in the absence of motor or sensory impairment.
[2] Partial or total loss of the ability to articulate ideas or comprehend spoken or written language, resulting from damage to the brain caused by injury or disease.
[3]A disorder marked by loss of the ability to write.

some cognitive dysfunction. Patients were not approached for entry into the study if dementia or other cognitive impairment had been already recorded in patient's notes.

A criticism of the questionnaire is that mild or early dementia may score as normal and vice versa *i.e.,* mildly affected individuals may be falsely labeled as having dementia.. It can not be used where there is dysphasia, deafness, depression, disturbed consciousness, native language difficulties and severe illness when the person cannot cooperate (Health Information Website, 2000).

The MSQ was used over any other systems (Global Deterioration Scale, Blessed Dementia Scale, Clinical Dementia Rating, Cognitive Levels Scale and Cognitive Capacity screening Examination) as it is considered the most established system in clinical researches of this type in the UK.

2.2.2 Designing of the Counselling Checklist

An essential part of this study was to attempt to improve patient's compliance and drug knowledge. Thus, a structured counselling technique was designed to achieve this and any counselling system used must be workable. This section describes the process by which this was achieved. Counselling checklists used in a similar context to that in the present study have been described in section 1.4.4 and section 1.5. There does not appear to be any single well validated tool but that by Coombes and Horne (1994) does seem reasonably comprehensive and also was reported as workable in the context of medication counselling for the elderly. The system used in this study is similar to that by Cantrill and Clark (1992) with some modification in terms of layout and being able to capture baseline data.

The aim was to design a tool that could be employed to collect the data necessary for effective medication discharge planning and act as an aide-memoir regarding medicine information to be given to the patient. The checklist was designed as a two-sided A4 sheet (Appendix II). The first side included all the patient's background details (name, age, gender, ward, bed number, date of admission, reasons of admissions, allergy status, past medical history, drug history, name and addresses of GP and community pharmacist and social status). In addition, this side contained all the information regarding the patient's discharge procedure (date of planned discharge, destination to which the patient will be discharged to, help received at home and medication on discharge).

On the second side of the checklist, there are small boxes to be ticked by the investigator; each box corresponding to a piece of information needed to be covered by the investigator during the counselling session. There is also a space in the checklist to note down problems, questions or concerns the patient may have during the counselling session. Another section is a checklist to ensure that the patient can recall the information provided. The last part of the checklist was designed to indicate the patient's physical ability to administer medicines *e.g.*, open bottles, remove the tablets or capsules out of the blisters or to use an inhaler device. This checklist was designed to be easily used by hospital staff other than the ward pharmacists *e.g.*, nurses, pharmacy technicians or pharmacy students.

2.2.3 Quality of Life and Nottingham Health Profile

The goal of healthcare is to prolong the lives of people and to improve the quality of their lives and with an increasing incidence of chronic diseases ways of measuring and assessing quality of life is an important area. Clinical measurements do not tell the whole truth about the way people cope with their conditions and the quality of their lives, because these matters have not often been investigated in relation to people's everyday life and environment. Quality of life measurements have emerged as an increasingly important criterion for evaluating the outcomes of treatment interventions. The concept "quality of life" encompasses a wide range of physical and psychological characteristics and limitations which describe that person's ability to function and to derive satisfaction from doing so. Quality of life is defined as "*the individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns*" (WHOQoL Group, 1993).

Quality of life is a broad concept which is affected in different ways by the person's physical health, psychological state, level of independence, social relationships, and their relationships to salient features of their environment (Bowling, 1995). Quality of life reflects life experiences, significant life events and the current phase of life. The factors defining quality of life include: sex; socioeconomic status; age and generation (Farguhar, 1995). Quality of life instruments have a number of uses and one of these is in evaluating the health services particularly as endpoints in clinical research, such as assessments of the influence of interventions (Velanovich, 1999). However, total quality of life is difficult to measure and may not always be necessary, so the narrower concept of "health-related quality of life" is often used. Self-administered questionnaires and structured interviews are the two most commonly used techniques to assess patient's quality of life (Jenkinson and Fitzpatrick, 1990).

In order to be useful for research and clinical applications, health-related quality of life measures need to have 5 essential characteristics that determine their quality (Velanovich, 1999 and Francis, 2001) although some of these are true of any questionnaire:

1. Reliability: which describes the extent to which the instrument yields the same number or score each time it is administered. It can be measured either by test-retest scores or by test-retest agreement on repeat administration under identical conditions or measuring degree of agreement between halves of the instruments as a single administration.

2. Validity: refers to the degree to which the instrument reflects what it is supposed to measure rather than something else. Validity can be content or face validity, *i.e.*, cover the areas of interest, and show similar (convergent validity) or opposite (divergent validity) relationships with other appropriate measurements and to be able to discriminate groups of people (discriminative validity).

3. Responsiveness or sensitivity to change: which measures the extent to which scores change when the concept under study improves or deteriorates *i.e.*, the ability of a tool to detect small but clinically important variations.

4. Appropriateness: where the instrument must be appropriate for the health problem and the likely range of effects of the treatment being investigated.

5. Practicality: which refers to the ease with which the instrument can be used.

There are three basic types of quality of life instruments: generic (addressing all aspects of HRQL), disease specific (dedicated to a particular disease or group of patients) and symptom severity (Velanovich, 1999). For the purpose of this study it is more appropriate to use a generic instrument because of its ability to be broadly applicable across a wide range of types and diversity of illness and across different medical treatments or health interventions (Velanovich, 1999). Generic health measures focus on functional status and well-being and are used in studies where one wishes to draw conclusions about general outcomes. One of the advantages of these measures is their ability to cover broadly different areas of life which maximizes the opportunity for detecting unexpected or iatrogenic effects (Francis, 2001). No one quality of life instrument fits all situations but the instrument chosen must be reliable, valid, responsive, practical and previously applied in a sample of elderly patients. With these

characteristics only a few instruments can be considered and one of these instruments is the Nottingham Health Profile (NHP).

The Nottingham Health Profile (NHP) was developed by a team in the department of community health at Nottingham University in the late 1970s (McEwen, 1993). The Nottingham Health Profile is a questionnaire, which measures the subject's health status in 38 statements that best reflect problems with health cover six areas; physical mobility (8 statements), sleep (5 statements), pain (8 statements), emotional reactions (9 statements), social isolation (5 statements) and energy level (3 statements). Within each area statements have been weighted using Thurstone method of paired comparison. This allows empirical judgments to be based on perceived differences (McEwen, 1993).

The following advantages have been recognized for NHP:

a. Suitability for wide range of situations from individual clinical interviews to large scale postal survey.
b. Can be self- or interview administered and has been used in postal surbeys.
c. High reliability and validity.
d. Short, easy and cheap to use and is highly acceptable to respondents.
e. Easy to score and compute. Particularly suitable for experimental analysis using the Statistical Package for the Social Sciences (SPSS).
f. Because of the indirect nature of the questions, it is more likely to pick up people who are ill or at risk but who do not perceive their problems as being related to health.
g. Scores provide profiles which differ for different medical conditions.
h. Can be of use to measure both general perceived health status and for specific medical conditions.
i. Age, sex and social class 'norms' are available for comparison.
j. NHP makes relatively small demands on patients' time

McDowell and Newell (1987) described the NHP and reviewed the different validation studies. The test-retest reliability was performed in studies on patients with arthritis and peripheral vascular diseases and it is proved to be of high value (0.75-0.8).

The validity of the NHP instrument in measuring the quality of life in elderly patients has been evaluated, where construct validity was assessed by observing the power of the scores to discriminate between four groups of elderly with different health status (Hunt *et al.*, 1980). The first group was composed of 50 physiologically fit men; the second had 28 fit participants, the third had 49 subjects suffering from some degree of disability and the fourth comprised of 86 chronically ill patients. To overcome the problems of eyesight or failure to mark the appropriate boxes, subjects were asked to read the questions while the researcher read the statements loudly to them. Statistical analysis of the data showed significant difference among the four groups in the six sections of the profile.

The general Nottingham Health Profile instrument was chosen for this study because it can be used to compare the quality of life with different diseases and comparisons can also be made with the general population. The application of the instrument in this study involves asking the patients to answer 38 questions regarding their health (Appendix III). Subjects are asked to judge each statement in a section against every other statement in that section in terms of which condition or situation they considered to be worst. The respondent is asked to reply "YES" if the general statement applies to his/her current status and "NO" if the statement is not true. The scores are weighted and added together within each section to give maximum of 100 for any group. A patient who has no health problems on the pain dimension, for example, is given an index value of 0 on this dimension, while a patient who has all the health problems mentioned on that dimension receives a total of 100. Thus a score of 100 means that all the questions within a group were affirmed (McDowell and Newell, 1987).

There has been much debate concerning the most accurate tool to be used in assessing quality of life. As the patients recruited in this study were suffering from various medical problems and were discharged with different prescribed medication, a generic tool would seem the most appropriate to assess the quality of life. Due to large variations between the different instruments that can be used to measure quality of life (QoL) and variations in the domains that each instrument covers, together with the difference in the techniques used to assess

reliability and validity of different instruments, comparing these instruments can be quite difficult. Also different instruments have different ways of scoring their domains. Of those other instrument that could have been adopted in this study and is proven to be reliable and valid, is the Short Form Health Survey Questionnaire (SF-36). SF-36 is a self-administered generic 36-item instrument which measures eight health concepts that are categorized into three major health attributes:

1. Functional status (*i.e.* physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems).

2. Well-being (mental health, vitality, bodily pain).

3. General health perception (an overall evaluation of health).

It also includes a global evaluation of health. Score for each of the eight health concepts are standardized to range from 0 (poorest well-being) to 100 (highest well-being) (Bouchet *et al.*, 2000). The SF-36 has been widely validated in the English language (McHorney *et al,*. 1994).

Prieto *et al.* (1997) reported that the SF36 is more reliable than NHP in that the discriminant validity of the two instruments was comparable in the cases of patients presenting chronic respiratory disease. Others (Essink-Bot *et al.*, 1997) reported that the internal consistency of the SF-36 was higher than the NHP scales and the SF-36 exhibited the best ability to discriminate between groups. Essink-Bot *et al.*, (1997) also favoured the SF-36 because of its psychometric properties when used in health population. The main advantage of the NHP over SF-36 for this study was mainly in the ease of administration of NHP where the elderly patients need to answer with only YES/NO rather than a 5-point Likert Scale for the SF-36, although some (Kind and Carr-Hill, 1987) have criticized the NHP as having lower sensitivity to change, probably owing to its use of the binary responses (0 or 1). This instrument was not used in the present study due to the difficulties of explaining the 5-point Likert scale, *i.e.*, similar to the problems identified in the pilot study for the *SIMS* (Section 3.9.4).

In the present study and because of the nature of the patients and the use of different questionnaires and interviews, it was important to consider only short instruments. Because of this, the Sickness Impact Profile (SIP) was not considered although it is proven to be reliable, valid, practical and sensitive. SIP may take longer time to complete it and may increase the numbers of patients dropping out the study. This was crucial in view of the quite lengthy assessment protocol to be employed. This instrument covers 12 aspects (ambulation, mobility, body care, social interaction, emotional behaviour, alertness, communication, work, sleep/rest, eating, home management and recreation) represented in 136 weighted statements describing behaviours related to health.

The SIP was developed in the USA with similar objectives to the NHP to provide a broad measure of self-assessed health-related behaviour. Unlike the NHP the SIP asks the respondent to make a judgement as to whether a problem is health-related. This may be difficult for elderly people uncertain of the distribution between effects of ill health and "natural" consequences of aging. The advantage of the SIP is that it is comprehensive and includes dimensions especially relevant to elderly people in the community (Fletcher *et al.*, 1992).

Another instrument used previously in this field is the Southampton Self-esteem Scale (SES). There is insufficient experience with this instrument at present and especially relating to responsiveness to change. Life Satisfaction Index (LSIA) is another instrument developed in the USA and it has been extensively used in elderly populations. The main disadvantage of this tool is the number of variants of the scale, the overall face validity of the questionnaire as an evaluation instrument and the lack of responsiveness to change in randomized trials. Both instruments are unidimensional subjective tools (Fletcher *et al.*, 1992). It would be of interest to assign a study to identify the most suitable tool for the elderly chronically ill population.

2.2.4 Patient Knowledge Questionnaire

The general area of attempting to improve and assess compliance and drug knowledge was discussed in chapter 1. An essential part of the present study is to attempt to improve patient compliance and drug knowledge; thus it was important to determine the patient knowledge baseline during his/her hospital stay and before receiving any counselling sessions.

A structured verbal questionnaire was used to elicit information about medications. Wherever possible all medications held by the patient at the time of the visit were inspected, including those prescribed before hospital admission if available and those obtained from the general practitioner after discharge, together with any OTC products. The prescription issued on discharge and the medicines actually being taken by the patient at home after discharge were compared.

There is no one universally recognized and validated form or questionnaire available for assessing patients' knowledge about their medication. Studies involving the assessment of medication knowledge have been fully discussed in sections 1.4 and 1.5. It was concluded that no well-validated questionnaire exists and each appears to be individualized for the purpose of that particular study. The aim of this study was to measure the change (improvement or decline) in patients' knowledge rather than measuring the absolute patients' knowledge. For this purpose it was important to use a questionnaire which is capable of covering the most important areas of information.

After identifying the potential candidates, all the patients were interviewed to elicit patients understanding of their medication regimen including names, purposes, shapes, colour, strength, doses, dosage frequencies, administration time, duration of treatment, special instructions and side effects for each of the prescribed he/she was taking at the time of admission. The questions in the structured questionnaire used to assess patient's understanding of the purpose of their medication, were based on one used in a previous study (Ryan and Chambers, 2000) which appeared to cover the most important points. The questionnaire used is composed of 29 questions as shown in Appendix IV. The accuracy of the information was assessed by comparing the details provided by the patients with the

information supplied by the hospital or from the information printed on the container labels if available as well as TTO transcripts.

A further reason for adopting the questionnaire was that it is one of the few tools where at least some validation of content has been attempted (Ryan and Chambers, 2000), where the researcher conducted a study to evaluate the effectiveness of an individualized education programmed on the knowledge of older patients regarding prescribed medication. This questionnaire was piloted on 15 patients in an Assessment and Rehabilitation Unit in Northern Ireland. Before applying this questionnaire on the actual patients, content validation was conducted by sending six copies to six experts in this field. Five experts replied back with some recommendations for revision suggesting that the questionnaire can be used as a valid tool to measure patient's medication knowledge. The questionnaire was also initially piloted on five patients which resulted in further minor changes to the structure and the wording of the questionnaire. The questionnaire used in the present study was piloted on ten patients and again only minor changes in the formatting and wording were required, for instance, patients found it difficult to understand the term "contra-indication".

2.2.5 Patients Compliance and Tablet Count

Compliance was defined as "*patient's adherence to directions on the prescription container label*". When the patients do not take the medication as prescribed, the behaviour was considered non-compliant (Wolfe and Schirm, 1992).

Tablet count is the traditional method for assessing compliance and one of the easiest to arrange. Tablet counts have for many years been the 'Gold Standard' by which compliance levels have been measured and usually involve the counting of dosage units left in the container after a certain period of time following dispensing. The compliance percentage is then defined as a percentage of the prescribed medication intended:

$$\% \text{ Compliance} = \frac{\text{Number dispensed-Number Remaining}}{\text{Number that should have been taken}} \times 100$$

Tablet counts can provide a measure of patient compliance and are accomplished by requesting the patient to bring their medication containers with them to their next appointment or show all the medication they keep at home during a domiciliary visit. Some researchers have also found it more desirable to contact the patient by telephone in their home and ask them to count the remaining tablets or capsules in the container.

The main advantages of using this technique are:

a. Simple, cheap and easy to apply.
b. Suitability for patients on various and numerous medications.
c. Makes relatively small demands on patients' time.
d. Provides quantitative results which can be used for further comparisons.
e. It allows compliance to be tested without the patients being aware that they were under close observation.

The widely used tablet count method (or more accurately a dosage unit count) has a number of well-recognized potential defects:

a. *Dumping*: Although tablets may have been removed from the container, they may not have been administered and disposed or hidden from the investigator before the next assessment.

b. Tablet counts give little impression of timing of doses or drug-free intervals. To overcome this problem, patients should not be supplied with the precise number of doses needed but with excess number of tablets (Raynor, 1992).

c. *Drift in therapy*: If tablet counts are performed at monthly or longer intervals, there may have been periods when compliance was very low and others where it was very high or even excessive. Tablet counts only measure whether the correct number of tablets has been taken, and do not measure compliance with dose or dose frequency. The patient could always underdose and then overdose, yet appear to be compliant.

d. Time consuming process and may rely on patients bringing back their tablets.

e. Results may be confused if medication is obtained from more than one source *e.g.*, GP and hospital.

f. Mislaid or forgotten bottles, which may actually have been deliberately left behind by the patient before the visit. Visiting patients at home would minimize the numbers of bottles not available for counting and the counting process is best performed in the patient's own home where all supplies can be located and accounted for. Even in this situation there is a possibility of patients not disclosing all supplies.

The Drifts in therapy have been described in one study (Rudd *et al.*, 1990) involving weekly tablets counts with hypertensive patients. Although the mean rate of compliance over the twelve-week study period approached 100%, there was considerable inter- and intra- subject variability in the weekly counts, which seemed consistent with 'tablet' dumping. Similar

drifts in compliance have been detected for tuberculosis therapy and treatment of urinary tract infections (Cheung *et al.*, 1988a).

Despite these drawbacks, many estimates of extent of compliance come from tablet counts (Raynor, 1992). Pearson (1982), stated in a review of methods for assessing compliance, while concluding that no method is completely effective "*though the corollary does not necessarily hold true, one single fact remains a beacon: if the tablets are in the bottle, they are not in the patient*". He concluded that tablet counts were useful, providing their limitations were recognized. Tablet counts correlate well with other methods of measurement. It is probably the most appropriate quantitative method of measuring compliance in patients taking several drugs (Raynor *et al.*, 1993)

To assess the effect of patient counselling on their compliance, tablet counting was used *i.e.* the percentage of prescribed doses, which were actually taken. A tablet count was used in this study as it is the only practical method when large numbers of patients taking a wide variety of medicines are investigated. Compliance assessed by the tablet count is based on the assumption that all the tablets were taken from the containers and none other were consumed by the patients and none given to someone else. The dosage units of each item dispensed were obtained from the label on the container if applicable and comparing it with the patient's copy of the TTO.

An alternative method to estimate patients adherence is the self-reporting questionnaire *e.g.*, Medication Adherence Report Scale MARS. Although this tool has been proven to be a reliable and valid method to assess patient's medication taking behaviour, it was not the most suitable technique to be employed in this study for various reasons:

a. Time consuming for both the investigator and the patients.
b. Quite subjective in nature.
c. Patients normally overestimate their adherence to their medication.
d. Elderly patients are often taking a large number of medications and it would be too time consuming to estimate each one.

Other questionnaire methods of assessing compliance are not well-validated. The electronic methods of compliance assessment were not within the resources of this study and would also not be practical for monitoring larger numbers of medicines in each patient. Likewise, blood level monitoring would not have been practical. Prescription refill monitoring is not a useful method in this situation where compliance needed to be assessed two weeks after reviewing discharge medication.

2.2.6 Patient Satisfaction

Providing patients with information about their prescribed medicines (*e.g.*, instructions for use, dose, route of administration, precautions, side effects and details of action to be taken in the event of wrong doses or accidental overuse) is essential to facilitate their appropriate use and an understanding of the likely benefits and risks (Baker *et al.*, 1991).

Patient information is an essential component of any effective treatment for chronic diseases. An important outcome of the effective medication education process is the extent to which the individual's needs have been met and they are satisfied with the information has been provided. It is important that the patient be satisfied with the information as it can be an indicator for quality of care. Assessing patients' satisfaction with the amount of medication information provided is one of the requirements for partnership in the use of medication (The Royal Pharmaceutical Society, 1997). Moreover, identifying the reasons behind patients dissatisfaction provides a key for interventions designed to tailor information provision schemes according to individual needs (Ali and Hone, 1996).

Although a certain minimum level of basic information is required by all the patients (*e.g.*, how to take the medicine), the absolute amount required will vary from patient to patient and from case to case. Patient reaction towards the information provided can also vary greatly. While some patients may be actively involved with the treatment process and seek detailed information about different aspects such as the possible side effects of their medicines, others will carefully respond, trying not to think about their illnesses and depending on carers to take the charge, finding additional information unhelpful or even confusing (Weinman, 1990). Providing patients with written information in a standardised form does not mean that the patient will follow the instructions of use the medication in the most appropriate way (Peveler *et al.*, 1999), as ideally the provision of information should be tailored to meet the needs and requirements of the patient.

One study conducted in South Thames (Ali and Horne, 1996) used a validated questionnaire known as the 'Satisfaction with Medicines Information Scale' (*SIMS*) to evaluate patients' perceptions of whether they have received sufficient information concerning the various

criteria that cover patient's needs. The *SIMS* questionnaire offers a novel method for measuring the degree to which the patient's information needs have been met. This scale can be used to identify the quality of information about medicines which needed to be provided to the patient. The *SIMS* could also be used to report patients satisfaction with the information they have received as part of their routine care and to identify improvement targets (Horne *et al.*, 2001b).

The *SIMS* can be considered as a valid and reliable tool for investigating the effect of interventions on satisfaction levels with information provided about medicines. Both in and outpatients were recruited from hospitals in London and Brighton to assess the *SIMS* validity and reliability. Criterion related validity of *SIMS* was performed in terms of relationships between scores on the *SIMS* and existing self-report measures of adherence called the Medication Adherence Report Scale (*MARS*) and patient beliefs about medicines (the Beliefs about Medicines Questionnaire (*BMQ)*) using Pearson correlation. The scale demonstrated acceptable internal consistency among patients from a variety of diagnostic categories (Cronbach's alpha was calculated and found to range from 0.61-0.91). Test-retest reliability was satisfactory in most of the groups tested. The acceptability of the tool was proven to be as high as 81% of respondents (Horne *et al.*, 2001b).

The *SIMS* has other advantages relevant to this study:

- It is broadly predicts self-reported adherence.
- It is simple, quick to administer and easy to record the finding.

Individual variations between patients' own views about the medication information they have received were considered when this scale was designed, rather than measuring the absolute value or quality of that information. This can help prescribers in tailoring individual education sessions that meet the needs of the every patient. *SIMS* is not just a research tool and the developers have suggested that it can be used in practice to identify the patients' information needs. Patient's level of dissatisfaction with the information can also be measured and addressed (Horne *et al.*, 2001b).

The *SIMS* consists of 17 items dealing with different types of medicines information that patients should receive to improve medication-taking behaviour. Each item is phrased in the form of a question that a patient might typically ask about their medication, *e.g.*, How to use it; for how long will I need to take this; what to do if I forget to miss a dose; what are the common side-effects.

Patients are asked to rate the amount of information they have received about each item on a five-point Likert type scale: none needed, about right, too much, too little, none received. The responses can be analysed in various ways. One way is using a *total satisfaction rating* that is calculated by summing the scores for all the items. When patients express satisfaction with the information covering a particular medication criteria, they are given a score of 1 *i.e.*, with a rating of 'about right' or 'none needed'. If the patient is dissatisfied with the amount of information received *i.e.*, with a rating of 'too much', 'too little' or 'none received', this is given a score of zero. Scores range from 0 to 17, with high scores indicating a high degree of total satisfaction with the amount of medication information received. Another way of analyzing the score is calculating *two sub-scale scores* that includes identifying patients' satisfaction with information about the action and usage of medication (items 1-9), and the potential problems of medication (items 10-17). The final method is a *detailed medicine information profile*, which can be performed by examining the ratings for each individual item, to identify individual information that needed (Horne *et al.*, 2001b).

Other instruments to measure satisfaction have been developed and tested. A self-assessment questionnaire was developed specifically for a study by Haggmark *et al.* (2001) in order to test the efficacy of various information inputs among three different groups receiving radiotherapy: standard information plus group and repeated individual information, standard information plus brochure, and standard information only. Visual analogue scales were used to allow the patients to describe on a 0-100mm line, their satisfaction with the information ranging from "not at all satisfied" to "completely satisfied". This instrument was composed of seven questions concerning satisfaction with information concerning radiotherapy.

The *SIMS* has been used in its entirety for this project (Appendix V). The total score rating will be adopted as the most reasonable way of analyzing the patients' answers as all the patients were taking more than one medication and it would be difficult to calculate the score for each individual medicine.

2.2.7 Classification of Medication-Related Problems

Two different classification systems were used to categorize the different medication-related problems reported in this study. The PCNE system was chosen because of its ability to classify the problems, their causes and the interventions performed to solve the identified problems. Also, this system is more detailed in pinpointing a broad range of problems due to large numbers of sub-categories included in this system. The PCNE system cannot assess the problems according to the degree of severity. Also, some of the identified problems did not have direct clinical impact on the patients and could not be classified according to a severity scale or even according to the PCNE system. That is why the second system was chosen, because of its ability to rate the identified problems according to the degree of the severity or according to the source of the problems whether clinical or non-clinical in origin.

2.2.7.1 PCNE System

This system was originally created in 1999 by the pharmacy practice researchers during a work conference of the Pharmaceutical Care Network Europe (PCNE) in a trial to develop and standardize a comprehensive and useable classification system. This system has an advantage over other existing systems that it separates the problems from the causes and the interventions. The following definition of MRPs is the basis on which this classification was designed: "*being potentially harmful to the patient's health or which may prevent the patient from achieving the full therapeutic effect of the drug used"* (Schaefer, 2002). The validation of this scheme focused on the following criteria: internal consistency, content and construct validity, inter-rater reliability, and the usability in research and practice settings. Construct validation of this system was performed by handing the standardised questionnaire to different research centers in different countries. Completed forms were returned to the national research centre where data was analysed. Reliability of the system was assessed using inter-rater reliability, internal consistency and international reliability. The system was well received by different users proving its practicality (Van Mil, 2001).

Classification system version 1.2 was adopted and adjusted (following PCNE approval) for the pilot intervention of pharmacy based disease management programme (DM) in Portugal. Version 3 appeared in 2002 on the internet after a revision by experts from different

countries. Version 4 was first published in 2003 on the internet again after it had been validated in Portugal, Northern Ireland and Malta. The current version is V5 is compatible with previous versions although new items have been added.

The basic classification has six primary domains for problems (Appendix VI), six primary domains for causes (Appendix VII) and five primary domains for interventions (Appendix VIII). Each problem should be coded separately, but there may be more than one cause or intervention related to the same problem (PCNE website).

PCNE system depends mainly on classifying the MRPs of clinical effect rather than any service related effect, and because of the inability of this system to measure the severity of the identified MRPs, the following system is adopted to overcome these two problems.

2.2.7.2 Medicine or Service-Related Problems Classification System

This classification is a novel system inspired from another classification used in a study carried out by Dean and Barber (1999) and Gordon *et al.* (1999). This classification divides MRPs into two major classes; those with medicine-related effects and those with services-related effects. Each class is divided into various subclasses. Each subclass is given a score which will be used to weigh the MRPs quantitatively.

I. MRPs with Medicine-Related Effect on the Patient

This class is divided into three categories; *minor*, *Moderate*, and *severe*.

a. Minor:

Definition: Very unlikely to have any adverse effects.

Score=1

This category includes all the MRPs that may be threatening patient's care with little effect, self-limiting, can be avoided by dose or regimen modification or by admixing another medication. Any problem belonging to this class is given a score of one (*e.g.*, constipation caused by DHC or cold Extremities with Atenolol).

b. Moderate:

Definition: Likely to cause some adverse effects or may interfere with the therapeutic goal of the regimen but very unlikely to result in death or long-lasting impairment or patient's hospitalization.

Score=2

This category includes all the MRPs that may be threatening patient's care but it is not life threatening, persistent, may need to stop that medication and to use an alternative medication. It may affect patient's compliance or affect the patient's quality of life. Any problem belonging to this class will be a given a score of two (*e.g.*, nausea and vomiting caused by Digoxin, diarrhoea caused by many medicines).

c. Severe

Definition: Likely to cause death or long-lasting impairment or patient's hospitalization.

Score=3

This category includes all the MRPs that may be threatening patient's life, may cause hospital readmission, or long-term effect on clinical efficacy. Any problem belonging to this class is given a score of three (*e.g.*, using NSAID with a history of peptic ulcer, or using Metformin in renal impairment or bleeding caused by Warfarin).

II. MRPs with Service-Related Origin

There is a potential problem but it is not affecting the patient's quality of life. This class is divided into seven categories.

a. Polypharmacy: This includes all patients' concerns or confusion because of using many medicines.

b. Interface Issues: this includes all the problems regarding the transfer of the information between the secondary and the primary care, with consequences of mistakes in medications

to be prescribed in the community (*e.g.*, repeating old medications being discontinued in the hospital or not re-prescribing newly prescribed medicines during the hospital stay).

c. ***Patient Knowledge***: This covers all the problems related to patient knowledge or information regarding their medication which may affect their medication-taking behaviour (*e.g.*, taking medicines before or after food.)

d. Physical Difficulties: This covers all the difficulties in opening bottles, swallowing the tablets or getting the tablets out of the strips, reading the label or using the inhalers.
e. Mistakes in the Labels: Discrepancies in the instructions written on the medicines containers or bottles or unclear instruction.

f. Compliance and Memory Problems: Forgetfulness which may lead to either under or over usage of the medication (non-intentional compliance). Also this includes the possibility of intentional non-compliance.

g. Storage Problems: Poor storage conditions (*e.g.*, keeping the medicines under the sink, or mixing all the strips of one medicine in one box, or taking all the tablets from the strips and putting it in one bottle).

Each problem which was categorised under any of the above classes in the service-related category was given a score of 1. Each problem was given a code which describing the class and the subclass. This code is composed of a roman number representing the main category (I. represents medicine-related category and II. Represents service-related) and this roman number is coupled with another English letter which represents the subclass *e.g.*, (Ia) represents minor medicine-related problem and (IIb) represents interface service-related problem. Some problems can be given more than one code *e.g.*, taking Aspirin on an empty can be considered as a moderate problem (Ib) and at the same time it can be considered as a knowledge problem (IIc). This simple method of classification was developed to have a quantitative measure to compare the effect of the discharge and follow-up scheme on minimizing the incidence of the MRPs.

As this is a novel model, it has not been validated previously and the reliability of this system was assessed by peer review. A case summary was written for each patient describing all the MRPs identified (Appendix IX). An electronic copy of these case summaries was given to the main supervisor (LG) who was invited to assess and rate the significance of the MRPs as identified for each case and give each problem a code using the above coding system. The second rater (LG) was completely unaware of the allocation of the patients to the two groups. All the data were analysed using SPSS software to test the reliability of these results.

CHAPTER THREE

PRELIMINARY FIELDWORK

CHAPTER THRR

Preliminary Fieldwork

3.1 Introduction

This chapter describes the preliminary fieldwork that contributed to the development of the protocol of the main study. Part of this work took place in the four wards of the Elderly Care Unit in St.Thomas' Hospital, London and the other part took place in the area covered by Lambeth, Southwark and Lewisham (LSL) primary care trust. This scoping study was undertaken to provide baseline data concerning the current provision of discharge services.

The researcher was an Egyptian qualified pharmacist who had recently finished her MSc. The undergraduate curriculum at her University contained little clinical pharmacy. Furthermore, clinical pharmacy is not widely practised and the healthcare system is very different in the primary/secondary care setting. The researcher therefore undertook clinical pharmacy training by attending relevant modules in the subject at King's College London. Intervention of some of the fieldwork described below was to help familiarize the researcher with the UK NHS system, particularly as it related to hospital discharge.

3.2 Aims

One aim of this preliminary fieldwork was to familiarize the researcher with the UK system regarding hospital discharge, the services provided, the various professions involved and the transfer of the service across the primary/secondary care interface.

3.3 Objectives

The main objectives of this preliminary fieldwork are:

1. To familiarize the investigator with the local discharge system and issues related to discharge medication and identify the current situation regarding patient discharge system at St.Thomas' Hospital, London.

2. To examine the range of medication-related problems presented to healthcare professionals concerning the hospital discharge of elderly patients.

3. To validate the investigator's ability to perform patient's counselling and deliver the required information.

3.4 Research Tools used in the Preliminary Fieldwork

Non-structured interviews were used to examine number of issues relating to the elderly patients, their hospital discharge and medicines. These interviews allowed the interviewees to freely express their views under the guidance of the interviewer. It was unnecessary to use structured or in-depth interview since greater detail was not required at this stage. This was not constructed as a true qualitative study, but simply a broad scoping exercise.

3.5 Survey of the Current Discharge Processes at St.Thomas' Hospital

Patients who are discharged from hospital may reasonably be expected to use their medicines most effectively if they are given information about the purpose of drug treatment and the anticipated benefits. To manage their medication supplies correctly they may also need information and advice about the anticipated duration of treatment, the source of continuing supply, the storage of medicines and disposal of unwanted medication (Cantrill and Clark, 1992). For the purposes of the current study, it was important to identify any patient medication counselling service offered to patients on discharge from St. Thomas' hospital.

3.5.1 Aim

The aim of this survey is to explore the discharge services provided by the ward pharmacists at St. Thomas' Hospital.

3.5.2 Method

The project investigator carried out this survey in the four elderly care wards in St.Thomas' Hospital. Because the data required was related to the services that the ward pharmacists should normally provide to their patients during the process of hospital discharge, they were not informed about the actual aim of the project. They were only informed that the project is concerned with the general discharging procedures carried out in the wards.

Collecting the data for this survey depended upon joining (observation study) one of the elderly care ward pharmacists or one of the MATeam (Medical Advice Team) while preparing the patient for hospital discharge and observing them collecting and checking the To Take Out (TTOs) medication forms as well as observing any counselling sessions with the patients. Pharmacists varied in their grades from C-grade to basic grade pharmacists. Part of this survey involved monitoring any counselling was performed by any of the nursing staff when this was feasible.

The investigator maintained list of patients for whom a discharge date had been arranged. All the relevant demographic data (name, age, gender, allergy status, date of admission, address, name of GP, address of GP, reasons for admission, past medical history, drug history and date of discharge) was noted, in addition to details of all medication on the drug chart prior to discharge. After the ward pharmacist revised the TTO prescriptions for certain patients, four copies were printed out; one to be kept in the ward and filed in the patient's note, the second to be sent to the pharmacy, the third to be sent to patient's GP, and the last copy was given to the investigator. From this copy of the TTO the investigator listed all the medicines for discharge and compared them with those written in the patient's drug chart. After collecting all this data and after the medicines had been dispensed, the investigator joined the pharmacist during the medicine counselling sessions given to the patient. During these sessions, the investigator took notes on the information provided to the patients (name of the medicines, strengths, doses, side effects, special instructions and if there was any new medicine prescribed) and also the time the pharmacist spent with each patient during the counselling sessions was recorded.

3.5.3 Findings

This survey was conducted in a period of three months from May 2001 till August of the same year and it took place in the four wards of the Elderly Care Unit in St.Thomas' Hospital, London.

Several techniques can be used to estimate the extent of patient counselling including: self-completion questionnaires, diaries and direct observation. Direct observation being used in

this pilot work as it is considered the most reliable method. The main advantage of this method is that it allows the investigators to 'see for themselves' which overcomes any bias can be precipitated in the self-reported questionnaires. This method may also give the investigator the chance to discover any "*behaviours or routines of which the participants themselves may not be aware*". The weakness of this technique is that the presence of the investigator may influence the participants' behaviour *i.e.*, encouraging them to perform more counselling (Aslanpour and Smith, 1997), sometimes referred to as the 'Hawthorne Effect'.

There were usually two pharmacists in the elderly care wards, a C-grade pharmacist and a basic grade pharmacist as well as occasionally a pre-registration student. The investigator was not able to monitor all the patients who were prepared for discharging as each pharmacist could potentially be involved at the same time. Also, due to the unplanned discharge, only half of those actually discharged were monitored by the investigator. This was in addition to those TTOs being prepared by the Medical Advice Team (MATeam) which is a team consists of C-grade pharmacist, basic grade pharmacist and a pharmacy technician. This team is responsible for any unplanned or delayed discharge taking place after 2:30pm.

Fifty five patients were monitored from a total of 90 who were discharged during the period of the survey. Out of those 55 patients, 37 (67.3%) were females. The mean length of their hospital stay was 29.84 (S.D=34.9) days with a range of 2-134 days, and the mean age was 82.02 years (S.D=8.78) with a range of 68-96 years. Although this survey was conducted in the elderly care unit there was one patient included in this survey aged 46 years who was admitted to the stroke unit which is one of the elderly care units.

Table 3.1 indicates the various destinations of patients following their discharge, from which it was noticed that more than half of the patients went to their own homes. The rest were discharged to other places, including nursing homes, residential homes, community centers or another hospital.

Table 3.1 Destinations of patients discharged from the hospital during the general survey

Destination	Home	Nursing Home	Residential Home	Community Center	Others	Unknown	Total
No. of Patients (%)	32(58)	11(20)	1(1.8)	1(1.8)	1(1.8)	9(16.4)	55

The investigator listed the various medical problems patients suffered before admission. Table 3.2 describes the different medical problems for which patients were receiving prescribed medication. The medical problems were categorized into seven major groups as shown in the table and most patients suffered from more than one medical problem. The most common reason for the hospital admission were falls.

Table 3.2 Frequencies and percents of the most commonly diagnosed medical problems among elderly patients in the elderly care unit in St.Thomas' hospital (N= 55)

Disease	No. of patients (%)
Cardiovascular Problems	44(80.1)
CVA[1] and Stroke	18(32.8)
Hypertension	11(20)
Angina	7(12.7)
Others	12(14.6)
Respirator Problem	11(19.9)
COPD[2]	7(12.7)
Other respiratory diseases	4(7.2)
Infections	21 (38.4)
UTI[3]	9(16.4)
Chest Infection	7(12.9)
Other Infectious Diseases	5(9.1)
Musculoskeletal Problems	14(25.5)
RA[4]	6(10.9)
OA[5]	5(9.1)
Central Nervous Problems	18(32.7)
Confusion	7(12.7)
Other Central Nervous Diseases	11(20)
Endocrinological Problems	13(23.6)
Diabetes	7(12.7)

[1] CVA= Cerebrovascular Accident
[2] COPD= Chronic Obstructive Pulmonary Diseases
[3] UTI= Urinary Tract Infections
[4] RA= Rheumatoid Arthritis
[5] OA= Osteoarthritis

Disease	**No. of patients (%)**
Thyroid Diseases	6(10.9)
Others	20(36.4)
Falls	17(30.9)
Anemia	3(5.5)

The patients left the hospital with an average number of 5.8 (S.D=2.9) medicines per patient, ranging from 1 medicine to 14 medicines. The 319 medicines were classified into thirteen major classes according to the British National Formulary (BNF) as shown in table 3.3. The most commonly prescribed medicines for elderly patients were anticoagulants and antiplatelets.

Table 3.3 Percentage distribution of medicines dispensed as TTOs (N=319)

Medicine Class	**No. (%)**
Gastrointestinal System	
Laxatives	32(10)
Proton Pump Inhibitors	15(4.7)
Other gastro-intestinal medicines	3(0.9)
Cardiovascular System	
Diuretics	17(5.3)
Beta blockers	6(1.8)
Drugs affecting rennin-angiotensin systems	7(2.2)
Nitrates	9(2.8)
Calcium channel blockers	9(2.8)
Anti-coagulant and antiplatelets	33(10.3)
Others	7(2.2)
Respiratory System	
Bronchodilators	15(4.7)
Other respiratory medicines	8(2.5)
Central Nervous System	
Hypnotics	7(2.2)
Antipsychotics	5(1.6)
Antidepressant drugs	9(2.8)
Non Opioid Analgesics	20(6.3)
Opioid Analgesics	7(2.2)
Antiepileptics & Antiparkinsonism	7(2.2)
Infections	
Antibiotics and other anti-infection drugs	8(2.5)
Antidiabetics	8(2.5)
Other endocrine medicines	11(3.5)
Gynaecology & Urinary Tract	5(1.6)

Medicine Class	**No. (%)**
Musculoskeletal and Joints	5(1.6)
Nutrition & Blood	
Vitamin D	16(5.0)
Other Vitamins	9(2.8)
Antianaemic medicines	6(1.9)
Food	6(1.9)
Others	29(9.1)
Eye Medicines	6(1.9)

Of the 55 patients discharged from the elderly care wards during this survey, 27 patients (49.1%) were counselled with an average time of 2.05 (S.D=3.12) minutes spent in counselling, 17 patients did not have any cognitive problems (as reported in patients' notes) and in spite of that they were not counselled before their hospital discharge. One patient was Turkish and did not speak English. Most of the medication counselling was carried out by one of the ward pharmacists or by one of the MATeam pharmacists, who generally prepare the TTOs for unplanned discharge. A minority of the counselling sessions were performed by the ward nurses (2 out of 55 patients were counselled by the nurses).

Table 3.4 Information provided to the patients during counselling sessions (N=27)

Information	**Number of Patients (%)**	
	All Medicines	**Some Medicine**
Names of medicines	5 (18.5)	17 (63.0)
Purposes of medicines	4 (14.8)	18 (66.6)
Doses of medicines	19 (70.4)	6 (22.2)
New medicines prescribed	9 (33.3)	5 (18.5)
Side effects	-	1 (3.7)

Among the counselled patients only 14% were offered an explanation about the purpose of the medication they were taking and 18.5% were verbally told the names of all the medications. The majority of the counselled patients (70%) were informed about the doses and frequencies. Thirty four (61.8%) patients out of the 55 were prescribed new medicines to take home and only 14 (51.9%) were informed that these medications were new.

Regarding the communication between the hospital (secondary care) and the community (primary care), a copy of the TTO with a case summary should be normally sent to the GP after hospital discharge by post. This copy is normally posted by the ward clerk and the time of sending depends on the clerk's work load. Communication with the community pharmacist is not part of the routine hospital discharge scheme and this fact was confirmed by the ward pharmacists.

During this survey, three basic grade pharmacists (two were males) in addition to the C-grade pharmacist (female) shared in preparing the patients for the discharge process. The investigator noticed great variation in the activities between the different pharmacists who carried out the counselling sessions during this period of time. They varied in the amount and the type of information they provided and the time they spent with the patients. The investigator noticed that the female pharmacists were much keener to carry out the counselling and to dedicate extra time to the patients. It was also observed that the ward pharmacists were involved in more than one task (patients' admissions, clinical rounds, patients' discharges and/or MATeam) at the same time, which was a barrier for some of them to give sufficient time for patient counselling. Members of the MATeam generally had less time to spend with the patients as they had to prepare more than one patient from different wards for discharge at the same time.

Below are three examples of the counselling sessions, which took place between ward pharmacists, and some patients before their hospital discharge; all the data and dialogues were recorded by the investigator during this survey. These examples indicate the somewhat superficial nature of these sessions.

Patient 41

Age: 82 years.
TTO:

Aspirin 75mg	OD
Becotide Inh. 100 mcg	2 Puffs BD
Amlodipine 5mg	OD
Salbutamol Inh.100mcg	2 Puffs QDS

Information provided by the pharmacist:

> ***"Hi, have you got your inhalers?***
> ***If you use this inhaler regularly, it won't relieve the attack but it will prevent the attack.***
> ***These tablets are for your blood pressure, take it for ten days, and then stop it".***

The patient brought her own Amlodipine with her but it was in a different package to that provided by the pharmacist, so the pharmacist said: "***This is the same as yours but in different package, it is the same & the same dose as yours".***

It is clear from the example mentioned above that, inhaler technique counselling was not checked before leaving the hospital. Also, the pharmacist relied on the fact that the patient had been taking all these medications before her admission and assumed that the patient was aware of the important details regarding her medicines.

Patient 45
Age: 95 years.
TTO:

Lansoprazole	15mg PD/OD
Ferrous Sulphate	200mg PO/OD

Pharmacist put the medication in patient's locker and no counselling was performed. It is very clear from this example that the patient did not receive any sort of medication counselling by the ward pharmacist, although the patient did not suffer from any cognitive problems and was totally independent.

Patient 52
Age: 87 years.
TTO:

Aspirin 75mg	OD
ISMN 60mg	OD
Frusemide 40mg	OD
Amlodipine 10mg	OD
Zopiclone 3.75mg	NOCT.
Amiodarone 100mg	OD
Adcal D3 2 tab	OD

Information provided by the pharmacist:

> ***"You've got fresh supply of everything except the Amlodipine as you have it at home as 10mg tablets which we don't have here, so you took your 10mg tablet this morning & from tomorrow use what you have at home***

This is your water tablet for your heart.
Calcichew is being switched to Adcal D3 both are the same & no differences
Zopiclone we don't have it in the hospital so make sure that you have it".

It is clear from this example that neither the doses nor frequencies or the reasons for taking those medicines were mentioned to the patient before going home.

3.5.4 Conclusion

From all the findings above and from the provided examples, there appears to be no structured patient counselling taking place in the elderly care wards in St. Thomas' Hospital. Insufficient time was allocated to provide enough information about each medicine a patient would be taking and realistically speaking, the 2 minutes on average is unlikely to achieve anything other than very superficial information exchange. More time should be spent with each patient to examine his/her abilities to open bottles and to take the tablets or the capsules out of the blisters or to use the inhalers properly. Patients also should be given the chance to ask questions and to query anything they do not understand and express their concerns regarding their medication. Also, from the informal discussions with nursing and pharmacy staff, it appeared that little formal patient medication education was undertaken during the patient's stay in the hospital. Finally, there was an obvious lack of communication between the hospital and the community pharmacists for sharing any information regarding the patient's medicines.

It was clear to the investigator that there was a great variation between the different pharmacists carried out the discharging processes, and these variations depended mainly on the availability of the staff and also on their enthusiasm.

3.6 Survey of the Opinions of the Healthcare Professionals

The second part of this preliminary scoping survey examines opinions of healthcare workers concerning seamless care related to medication and transfer of the information between primary and secondary care.

3.6.1 Aim

To identify some of the problems that may face the healthcare professionals in the community concerning the medication of patients following hospital discharge.

3.6.2 Method and Findings

Informal appointments were arranged with a community pharmacist, members of the Lambeth practice group team, a district nurse and a member of the delayed discharge team in Guys & St.Thomas' Hospital, London. Opinions of these healthcare members were obtained through open non-structured interviews. The interviews began by one simple question: "***what are the major problems you may face concerning discharge medication after patients leave the hospital?***" and then asking them what would they suggest to overcome these problems from their point of view. During these interviews all the responses were reported by hand. The interviews were not audio-taped.

Poor communication between the primary and the secondary care professionals was the major problem the community pharmacist faced during his career: ***"lack of communication between the hospital and community pharmacies represents the major problem, it is very useful to send a copy of the TTO to the community pharmacist to be aware of any changes that may occur to my customers, especially the regular customers and I keep a medical record for them".*** He also mentioned the importance of informing the patient of any new medications they are taking or any changes in their regimen and providing them with written materials supporting this information ***"The hospital can give a copy of the TTO to the patient to be aware of any changes that may occur to their medications".***

Members of Lambeth Practice Group agreed that the major problem is the poor communication between the primary and secondary healthcare members and the lack of

information provided to the primary care team ***"consultants do not describe in their letters why they made those changes in the patient's medications and whether the new medication is to be continued or not!!!".***

When the district nurse was asked to give her opinion concerning the problems she observed during the visits to her patients after their hospital discharge, she commented on the lack of complete information provided to the patients or their carers about their medicines. Also, the lack of communication between primary care and the secondary care was another problem, from her point of view, which she used to face every time the patient leaves the hospital ***"we hardly receive complete information concerning patients' medication and the changes occurred to them during their hospital stay".***

Finally the members of the delayed discharge team in Guy's hospital commented that one of the main problems after the hospital discharge is lack of the information provided to the patients prior to hospital discharge.

3.6.3 Conclusion

After meeting these professionals and discussing the problems they face after patients are discharged from hospital, the following can be concluded:

a. Patients leave hospital with insufficient information regarding their medication.
b. There is a lack of communication between primary care (GPs mainly) and secondary care professionals due to delay in sending the TTO in time, which may result in re-prescribing the old discontinued medications.
c. There is a lack of communication between the ward pharmacists and the community pharmacists.

From those three areas together with the problems identified after carrying out the general survey in the hospital, there is a potential need to improve patients' and/or their carers' knowledge of medicines and the links between the community and hospital healthcare professionals.

3.7 Assessment of the Counselling Checklist

After the checklist was designed, a validation exercise was carried out to examine whether it was practical for the investigator to cover all the aspect described on the form. In addition, it was important to ensure that the checklist was an accurate reflection of the information actually given to the patients.

3.7.1 Aim

Assessment of the investigator's skills and abilities to perform patient's counselling using the counselling checklist.

3.7.2 Assessment Process

The counselling procedure was piloted on ten different patients. Patients were selected from the elderly care wards in St.Thomas' Hospital. The criteria for entry were; elderly patients, over 65 years, prescribed at least one medication, mental cognition score sufficient for a conversation to take place and being capable of managing their own medicines by themselves or with minor support by carers.

Counselling was performed by the investigator using a standard protocol involving verbal instructions concerning the patient's regimen. The investigator was trained by the project co-supervisor (LC), who was the senior ward pharmacist in the same hospital on the correct use of the counselling protocol before starting the counselling sessions. The investigator rehearsed the actual counselling session in the presence of the senior pharmacist before talking to the patients. For each patient, two copies of the checklist were issued, one was given to the senior pharmacist in the elderly care unit in the hospital and the second copy was kept by the investigator. Each patient was counselled for about 15 minutes. The investigator counselled the patients using the checklist as a guideline for counselling procedure and for the information needed to be given to each patient. While the investigator was counselling the patients, the senior ward clinical pharmacist (LC) observed the investigator, using her checklist copy to mark all the points that she felt were correctly covered by the investigator. The investigator used her own copy to mark the areas she covered during the counselling

session. The two copies of the checklist were compared to identify which areas were adequately covered and if any item needed to be changed or edited.

3.7.3 Findings

The differences between the two checklists were compared (Appendix X) and discussed with the senior pharmacist to find out the reasons for any discrepancies. In some cases, it was inconvenient to cover all the categories for all the drugs *e.g.,* discussing all the possible side effects may confuse the patients, or it may sometimes be unnecessary to describe the strength of the medication. Also, because the assessment was sometimes performed on inpatients not yet ready for discharge, there might be no reason to inform them of the duration of the medication, disposing of the old medications, or other various instructions. In some cases no special instructions needed to be given to the patients regarding their medications.

During the assessment sessions, the senior pharmacist directed the researcher on the best way of providing the information to the patients, which expressions to use and which to avoid *e.g.,* using tummy rather than stomach, water tablets rather than diuretics, medicine to move your bowel rather than using the term laxative, and how to approach different patients in different ways according to the individual situation.

After piloting the checklist on ten patients and discussing the various points identified, the senior pharmacist affirmed the researcher's competence to undertake the counselling sessions. By the 10^{th} patient, it was very clear from the observed similarities between the two checklists that a good level of competence had been achieved.

3.8 Application for Ethical Committee Approval

After conducting the pilot work and the general survey, an application was made to the ethics committee in St.Thomas' hospital. All the application forms were filled by the investigator, revised by the main supervisor (LG) and the senior hospital pharmacist (LC) and applied for approval from the hospital committee (Appendix XI).

3.9 The Pilot Work

The instruments to be employed in this study consisted of: patient knowledge questionnaire, tablet counts, the Nottingham Health profile, *SIMS* questionnaire and the home visit checklist. This section describes a pilot study to assess the usability of these instruments before utilization in the main study and that the study protocol was practical and achievable.

3.9.1 Aim

The primary aim of this pilot study was to ensure that the tools for use in the main study were workable and practical in the setting in which they were to be used. A secondary aim was to identify any problems associated with the conduct of the study.

3.9.2 Sample Recruitment

Elderly patients were eligible for inclusion in the study if they were admitted to one of the four Elderly Care Unite wards in St. Thomas' hospital, English speaking, mentally stable, on more than one regular medication and gave informed consent to participate in the study. Patients were approached by the researcher and were given verbal details of the research. Patients were invited to take part; those who agreed to participate signed a consent form (Appendix XII). Recruited patients were randomly allocated to either intervention or control group. It was decided to randomize 10 patients for the purposes of the pilot and then follow through the entire study protocol.

3.9.3 Method

After seeking consent form approving to take part in this study, the 10 recruited patients therefore were followed in the same general scheme as described in the main study (Chapter VI), and involved the same assessment instruments. These are discussed in Chapter II and described in the corresponding appendices.

3.9.4 Results

The instruments piloted are those that would be significantly influenced by the counselling process which includes patients' knowledge, adherence to their medication regimen,

satisfaction with the information provided, quality of life and numbers and natures of medication-related problems.

Out of the 10 recruited patients, 5 were allocated to each group. Two patients failed to complete the second home visit. One patient refused to continue the study and the second patient was admitted to the hospital before the second assessment. This 20% dropout rate was used to inform calculations for the total number of patients to be recruited for the main study. Full results for each of the assessment parameters are not shown as the data would have little meaning as expressed as means for each group, owing to the small numbers of patients involved.

Compliance Assessment

The tablet count technique (Chapter 2) was used as the sole method for calculating patients' compliance to their medication 2 and 6 weeks post hospital discharge. The compliance score percent was calculated by dividing the actual number of tablets taken by the number that should have been taken multiplied by 100. It was difficult to assess compliance level for 4 control patients during the first home visit because they were using old stock they kept at home before their hospital admission. During the second home visit, the intervention group showed a compliance score of 80.7% compared to 73.0% reported for control group. Although it was difficult for the researcher to assess the compliance during the first home visit, this visit was essential to provide a baseline data for the types and the numbers of medication patients had at home and facilitate the tablet count for the second assessment.

Medication Knowledge

Patients of both the control and the intervention groups were assessed for their knowledge level concerning their medication during their hospital stay and two and six weeks post hospital discharge. Most of the questions used to assess patients knowledge were easily understood by the patients except a question regarding contra-indication as patients did not understand the word and the investigator had to explain its meaning for every patient.

Patients in the intervention group did improve their composite knowledge score (mean of 8 questions asked) between the baseline at 22.4% and the first visit at 45.2%, with little additional improvement by the second home visit. The control group did also appear to improve, but owing to the low numbers involved it is possible this result was an artifact.

Different methods can be used to express the patients' knowledge level and one of these methods is to calculate the percentage of the patients answering correctly for all of the questions about their medicines. The drawback of this method is its inability to measure its extent to which patients know about their medication. The second method that can be used to express the level of knowledge is to calculate the mean percent of the correct answers patients provided *e.g.*, when a patient gained a score of 100% concerning drug names, the patient had a full knowledge of all the names of drugs prescribed. This latter method is adopted in this study.

The questionnaire itself did not need any sort of editing except increasing the space provided for each question to include 10 different medications rather than six only as it was found that five patients out of the ten were taking more than six medications.

Quality of Life and Nottingham Health Profile (NHP)

The NHP was administered to the patients of both groups by a single interviewer using a standard technique. Patients were asked to answer the 38 questions of the profile regarding their health (Appendix III). Replies were weighted and then summed to give the final score for each of the six sections. The maximum score for each of the topics covered by the NHP is 100. Because of the both visual and physical difficulties patients may suffer, it was more convenient to read the questions to the patients and ask them to answer with YES/NO rather than asking them to fill the profile themselves.

Patients of both groups did not have any problems understanding the questions and answering them, although some of them expressed that it would be more convenient to have "SOMETIMES" as a third option. To overcome any confusion regarding answering the questions patients were advised to base their answers on the current situation on the day of

administering the questionnaire. Quite large standard deviations in scores were obtained so no conclusion could be drawn regarding any likely change in score as a result of counselling.

Patient Satisfaction with Information

Providing patients with information about their medication is an essential element of any successful therapy. One of the tools that can be used to assess the effectiveness of medication counselling process is to measure the extent of patient's satisfaction with the information provided during the education programme. The *SIMS* questionnaire (Appendix V) was used to assess the level of satisfaction with the information provided to the patient prior to their hospital discharge. Patients were asked to rate the amount of information they received concerning each of the 17 items of the questionnaire using one of five answers: about right, too much, too little, none needed or none received.

Some of the patients found it difficult to remember the five different answers they needed to rate their level of satisfaction. Therefore, five small cards (13cm X 8cm) were used to print the five scales using font 32. These cards were handed to the patients during the administration of the questionnaire to facilitate the process of answering the questions. The ten patients expressed embarrassment when they were asked question No. 16. The composite score for the intervention group was higher (mean 9.2, SD 6.1) than that of the control (mean 3.2, SD 2.2).

Identification and Classification of the Medication-Related Problems

During both the first and the second home visits, patients of both groups were asked to show all the medications in their possession. In a non-structured interview patients could express their concerns regarding any problem they thought might be related to their medication. After completion of the pilot study, a preliminary analysis was conducted on the MRPs identified. These categories were re-examined and refined. It was established that due to the wide range of problems, the MRPs could not be confined to a few categories. The problems were a summation of both what the patients expressed and what the investigator identified by reviewing the patients' medication and by asking the patients the questions that the investigator thought were the most relevant to their medication. Sixteen problem categories

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were identified during the first home visit (8 problems in each group), this number decreased to 3 problems during the second visit (all in the control group). The problems mainly concerned side effects, dosage errors, stopping necessary medication, duplication of medication, compliance problems, physical difficulties and label problems. Because of the small number of the patients and wide range of problems identified in this pilot study, it was difficult to form a classification system at this stage.

Conduct of study

No particular problems were identified in the recruitment process. It was established that attendance of the researcher at the hospital was required for five days a week to visit the wards and identify those to be discharged. It did not appear to be crucial regarding the time of attendance as ward staff were usually able to give sufficient warning concerning planned discharge. At the rate of recruitment it was possible to plan the domiciliary visits. After recruiting the first few patients of the pilot it became apparent that the rate would be too low for the timescale of the project if only relying on the Elderly Care Unit. An approach was made to the general medical wards where it was identified that patients were admitted who met the inclusion criteria and a proportion of these were also under the care of the geriatricians. With this additional source it would be possible to reach the sample size.

All the interviews were planned to be audio-recorded, but with recruiting the first patient, it was found that this idea was totally unacceptable and was confirmed by the rest of the ten patients. When patient consent, assessment and counselling was attempted in a single session before discharge it was found that the length of time required could be in excess of 45 minutes and this was unacceptable to some patients. Therefore, after two patients had undergone this process another system was instituted where consent and the Nottingham Health Profile where administered on the day prior to discharge, with counselling and knowledge assessments on the day of discharge. This reduced any one session to a maximum of around 30 minutes. Time taken during the home visits did not appear to be an issue for the patients in the pilot study, those who were more socially isolated appreciated the time the researcher spent talking to them. It is probable that the more relaxed and social setting of their own home helped improve communication with the researcher. It was feared that the

control patients would wish to discuss medication with the researcher, but this did not appear to be a significant problem.

Travel to patients' homes was achieved by public transport which meant that no more than two visits could be undertaken in a day. Also, due to the project limited time, all the home visits were arranged to be in the afternoon.

For the data collection information sheet, it was more convenient to design it in the simplest way to be easily used by any hospital staff including technicians. No editing or formatting took place to this form. Regarding the letters to be sent to the community pharmacists, it was advised by one of the contacted community pharmacists to add the name and contact number for the patient's GP.

3.9.5 Summary and Implication for the Main Study

The results from this preliminary fieldwork were used to inform the main study. By application of the different instruments on 10 different patients using the actual experiment setting, it was found that very minor modifications in wording and formatting of the various tools needed to be employed to produce the final form for the main study. The findings that informed the main study were:

1. Due to difficulties in getting a reasonable number of patients within the specified inclusion criteria from the Elderly Care Unit it was more convenient to extend the recruitment by including the elderly patients admitted to the general wards.

2. Due to visual and physical difficulties, all the questionnaires and interviews were administered by the investigator rather than using self-administration.

3. Due to similarities between the five different scales of the *SIMS* questionnaire and difficulties for the patients to remember them, five small cards were designed showing the five answers and these cards were handed to the patients to assist them answering the questions.

4. No one MRP classification system was chosen for use at this stage and the process of choosing one system was left until completion of the main study.

5. Differences in compliance and *SIMS* between the control and intervention groups after counselling did suggest that the study was appropriately powered concerning the numbers planned to be recruited.

6. One question regarding 'contraindications' was removed from the knowledge questionnaire.

7. More space was added to the knowledge questionnaire to accommodated ten medication per patient rather than six.

8. GP's name and contact number was added to the letters sent to the community pharmacists.

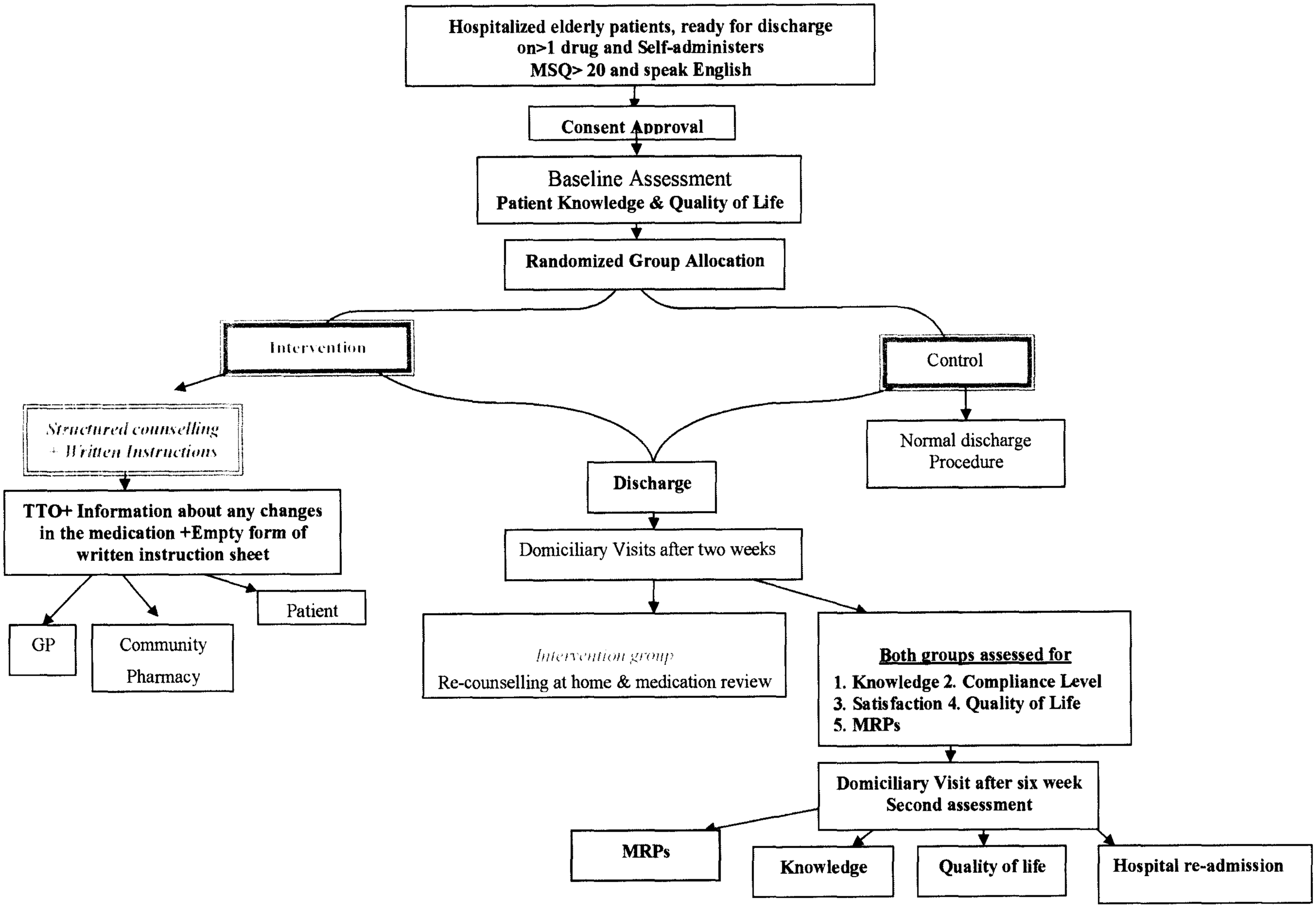
9. The pre-discharge sessions were managed over two days per patient rather than a single session on the day of discharge

These modifications are reflected in the final methodology for the main study in Chapter 4. Owing to the minor nature of these modifications it was reasonable to include the results obtained from the ten patients of the pilot study in the main study.

CHAPTER FOUR

PLAN OF PROJECT

Figure 4.1 Diagram of the Plan of Work



CHAPTER FOUR

PLAN OF PROJECT

4.1 Introduction

This project is designed to examine the effect of a hospital discharge and follow-up scheme in improving elderly patients' adherence and knowledge of medications, as well as identifying and reducing the identified medication-related problems (MRPs).

In addition to the pharmacist's task in monitoring the drug therapy of patients during their stay in the hospital, the ward pharmacist should also aim to take more responsibility in bridging the gap between the secondary and the primary care during patient discharge in order to ensure that the patient receives seamless care. Few studies have reviewed the liaison between the community and hospital pharmacists. This study took place in St. Thomas' hospital, London in the four wards of the Elderly care unit and three general wards. The post-discharge part of the study took place at patients' homes most in the Lambeth, Southwark and Lewisham (LSL) Care trust. The study approved by St. Thomas' Hospital Ethics Committees (Appendix XI).

A main focus of this study is to follow-up the patients post hospital discharge by carrying out domiciliary visits that enable further patient education and address poor adherence. The effects of patient education during the visits are presented in terms of adherence with prescribed medication, patient knowledge of their medicines, and patient satisfaction.

The central part of this study involves identifying, classifying and reducing potential medication-related problems in elderly patients soon after they leave the hospital. This has not been attempted within this context in other studies and therefore, represents the novel nature of this work as a contribution to existing knowledge concerning hospital discharge. The data from part of this study has been presented at both national (HSRPP) and international (FIP) conferences (Mohammed Safwat 2003a and b).

The project assesses a number of parameters used and one of the most important is the way in which patient's adherence can be improved by counselling. Linked to the area of patient adherence is the

measurement of changes in patient knowledge, patient satisfaction and quality of life. The second area involves monitoring the effect of the domiciliary visits on detecting the MRPs that develop post discharge and how hospital-based liaison pharmacists could intervene such problems.

The main study is a controlled randomized trial which is designed to demonstrate the effects of the patient medication counselling on elderly patients and the liaison with the healthcare professionals in the primary care setting to overcome the medication-related problems.

4.2 Aim

The overall aim of this project is to investigate the influence of a novel hospital discharge and follow-up scheme and try to smooth the transfer of the pharmaceutical care from the secondary to the primary care regarding the elderly patients' medications and any MRPs by assessing a number of variables that may be influenced by such scheme.

4.3 Objectives

The project has the following objectives:

1. To examine whether structured medication discharge planning education improves elderly patients' outcomes concerning knowledge and adherence to medications.

2. To develop and assess methods of overcoming interface issues concerning discharge medication in terms of improved communication with GPs and community pharmacists.

3. To explore whether the implementation of domiciliary visit schemes for elderly patients post discharge conducted by a hospital-based pharmacist liaison worker has any additional benefits over a pre-discharge counselling services.

4. To assess schemes for identifying, classifying and reducing potential MRPs experienced by elderly patients after hospital discharge.

4.4 Null Hypotheses

1. Patients who undertake structured discharge scheme have ***no better compliance*** to medication two and six weeks post hospital discharge compared to the control group.

2. Patients who undertake structured discharge scheme show ***no improvement in their quality of life*** two and six weeks post hospital discharge compared to the control group.

3. Patients who receive intensive education session prior to and two weeks after hospital discharge show ***no improvement in their knowledge*** about their medication two and six weeks post hospital discharge in comparison to the control patients who receive no further education.

4. Structured planned discharge scheme has ***no effect on a patient's satisfaction with information regarding their medicines*** for the intervention group compared to the control group two weeks post hospital discharge.

5. Patients who receive a structured discharge scheme show ***no difference regarding the numbers and the types of the medication-related problems*** they experience compared to the control group two and six weeks after hospital discharge.

4.5 Subjects

4.5.1 Selection

LSLHA was selected for the study because it was large health authority in south London that could provide the study with a diverse population. It has a population of various socio-economic status and ethnic cultures. This would provide the study with a sample of patients with a wide range of characteristics. Also, the geographical location ensured easy access to patients' homes. The following inclusion and exclusion criteria were used as guidelines to select the most appropriate candidates for this project.

Inclusion Criteria

a. Elderly patients were deemed eligible for the study if they were aged 65 years or over and admitted to one of the four elderly care units or one of the three general wards in St. Thomas' Hospital.

b. Patients must be responsible for administering their own medication and not regularly supervised by relatives, friends, carers or district nurse. This would mean that the patient was not visited by a nurse more than once a week or that a relative/ friend did not prompt every dose of medication.

c. The patients must be taking more than one regularly prescribed medication.

d. The patients must speak English.

e. The patients must be discharged to their own homes (not to institutionalized settings where they receive daily supervision).

f. The patients must agree to receive their medications from only one pharmacy of their choice.

Exclusion Criteria

a. Mental status questionnaire (MSQ) scores of less than 21.

b. If the patient was hospitalized less than 24 hours.

c. Patients discharged without any medication or when required only medication.

4.5.2 Patient Consent

All patients were consulted for written informed consent before entry to the study. The form (Appendix XII) was read out and explained for each patient before asking them to sign it.

4.5.3 Patients Randomization

Those giving written informed consent were independently randomized using computer-generated random numbers. Patients were assigned to either an intervention or control group. Recruited patients were unaware as to which group they had been allocated.

a. The *intervention group* (patients themselves and/or their carers) received a structured medication education (Appendix XIII) supplemented by a written aid (Appendix XIV) prior to hospital discharge. Patients were educated about the correct use of the medication and concordance issues. Where appropriate, MRPs were addressed and resolved.

b. The *control group* received the usual pharmaceutical care and discharging procedure provided in the hospital (Pharmacists and nurses are undertaking the usual activities).

Although not strictly a question of bias, it is possible that the randomization process adopted failed to identify enough individuals falling into the extremes to allow for a better understanding of the strength of the intervention. For example, compliance was generally very high so it would be difficult in the chosen design to assess the true benefits of counselling to these fewer individuals with poorer compliance. The answer would have been to stratify the randomization into appropriate numbers of poorer compliers to each group. This stratification technique as mentioned was not possible as baseline compliance was not known. Another approach would have been to use the NHP as a health status measure for the stratification *i.e.*, examining the benefits of the discharge process on those with either poorer or better health status. This would have been difficult as the total NHP score across all of the areas has no validity and stratification across the individual area would require a greater population. In addition, any cut-off point would have been purely arbitrary. Similar argument would have existed for the knowledge assessment. The final argument for the system is that it was not possible to power the study for health status regarding NHP or knowledge. A power calculation demands evidence from other studies regarding the confidence intervals of the findings and these were not available for these measures unlike compliance as assessed by tablet counts. A pilot study may have been able to power such a study, but the standard deviation from the NHP may indicate that the pilot would need to have been almost as large as the main study to confidently predict numbers of subjects.

4.5.4 Sample Size

The sample size was determined using the conventional value of five percent as the level of significance ("a" error). The outcomes to be measured in this study are:

Compliance.

Patient knowledge.

Patient satisfaction with the information provided.

Quality of life.

The identified medication-related problems.

Sample size was based upon tablet count rather than either the medication-related or health-related outcomes mentioned above. The Nottingham Health Profile could have been used but this was rejected because it was difficult to identify any similar studies from which to predict the variance as described above. The pilot study was too small on which to base any accurate power calculation. It was decided that the outcomes of the NHP would not be one of the primary outcome measures and not suitable for basing the power calculation. The medication-related problems could also have been used, although again the literature did not contain many similar validated studies upon which to base a calculation. In view of the large range of potential MRPs it would have been unreliable to use a small pilot study for the calculation. As constructing total MRPs score would have little meaning and be invalidated this was also rejected. The same reason was applicable for the knowledge score. It was also difficult to calculate the sample size counting on the *SIMS* score as it has not been used in the same context of this project. Over 20 similar studies were identified that had assessed compliance tablet count and this was used for the calculation.

The sample size recruited for this study was based on the following information:

1. According to studies a 5% difference in compliance between the control and the intervention groups would suggest significant difference between the two groups. Most observed mean 10-15% differences and recorded a standard deviation.

2. A drop out rate of about 20% was reported in the pilot study and was also reported in similar studies (Begley *et al.*, 1997).

3. Recruitment of 120 patients would provide the study with a sample size that could be managed by one investigator within the time frame of the study.

4. The sample size of the patients would fulfill the primary objective, *i.e.*, the sample would be large enough to show difference in compliance between the two groups that could be statistically and qualitatively analysed.

This would suggest that 52 subjects in each group would produce statistically significant results in terms of compliance. When including the potential dropout rate, 61 subjects per group would obtain statistically significant results at $P<0.05$ level.

4.6 Assessment of Baseline Data

4.6.1 Mental Status

Patients' cognitive functions and their suitability to take part in this project were assessed using the Mental Status Questionnaire (MSQ) which was described in chapter 3.

4.6.2 Demographic Data

Basic demographic information was collected (name, address, age, gender, name and address of the general practitioner, name and address of the community pharmacist). These details were documented from the patient's medical notes. Medical records were used to obtain other data including date of admission, the admitting diagnosis, drugs on admission, patient's medical history, patient's drug history, date of the planned discharge, the planned discharge medication, other diagnosis and level of care to be received in the community were all reported.

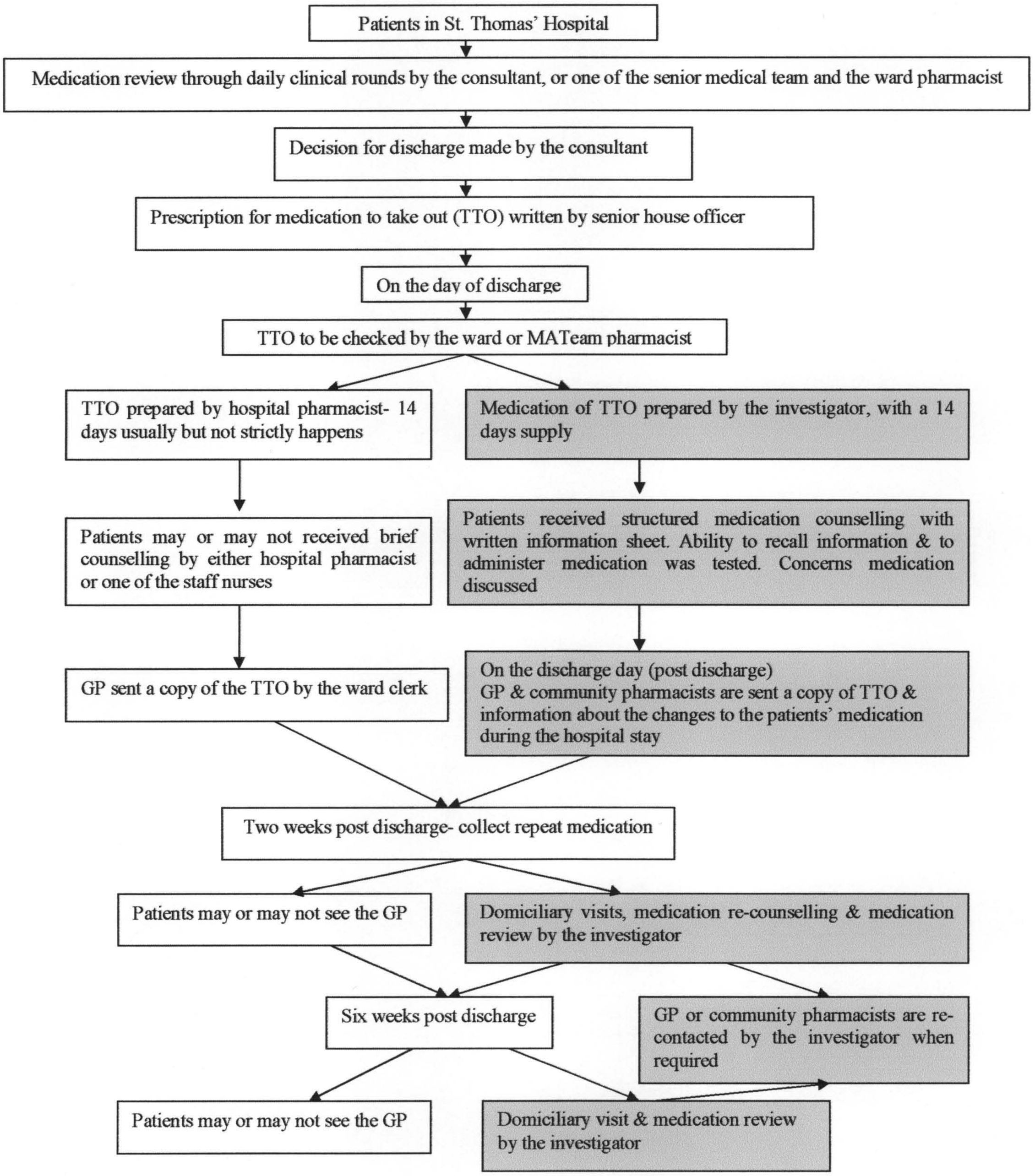
4.6.3 Nottingham Health Profile (NHP) and Measurement of the Quality of life (QoL)

In this study, health-related quality of life was approached in terms of patient's subjective health status using the Nottingham Health Profile (NHP) instrument. The NHP was administered to both groups by a single interviewer using a standard technique (Appendix III).

4.6.4 Patients Knowledge

After identifying the potential candidates, and prior to discharge from the hospital, patients were questioned regarding different medication aspects, to assess their knowledge levels in a variety of areas. Questions also include details of whether they had been informed about the number of the days' treatment supplied on discharge, whether they had been advised to obtain further supply from their general practitioner before the drugs provided by the hospital were finished and whether information had been supplied about the purpose of their drugs, when to take them, or possible side effects (Appendix IV). Questions were administered by face to face interview and the answers were recorded by the investigator.

Figure 4.2 Patient care pathways and an intervention pathway clarifying the process of care for each ggroup (intervention pathway shaded)



4.7 Methods in the Main Study

The study was divided into two phases:

The first phase of this study was conducted at St. Thomas' Hospital, in one of the four wards of the elderly care unit or one of the three general wards. The second phase of the study was conducted in the subjects' homes two and six weeks after hospital discharge. Prior to hospital discharge all the patients were assessed for the inclusion and exclusion criteria mentioned previously. The study is considered as a prospective randomised trial, with patients receiving the enhanced package of medication discharge services or receiving the currently provided services.

4.7.1 Phase I: St. Thomas' Hospital

Using the method described in Appendix (XIII) patients from the intervention group were educated regarding the correct use of their medication and adherence was encouraged appropriately. Prior to hospital discharge the intervention patients received one-on-one pre-discharge counselling session using standardized structured checklist concerning their medication (Appendix II). The importance of regular dosage and reasons for taking the medications was emphasized. Patients were informed about the most commonly occurring side effects. They were also told that they would receive only a 14 day supply of medication from the hospital and to ensure continuity of treatment, patients were informed about the importance of obtaining a further supply of medications from their GPs not later than fourteenth day after discharge. Patients were also advised about the regular visits to their GPs. The investigator asked the patients to stop using any medication they kept at home before the hospital admission and return them back to their pharmacist or their GPs. The importance of compliance was stressed together with the consequences of under or overuse of their medicines. The counselling session was carried out on the actual day of discharge by the patient's bedside. This time was selected in order for the researcher to discuss with the patients the medication they were to be taking home.

All the problems identified, actions taken and the length of time required for the interview were recorded. Patients in the intervention group were given the chance to ask any question, they were also tested for their ability to open the bottles, use the inhalers, and use the blister

packs. The researcher asked the patients appropriate questions to ensure they had remembered the information.

In addition to the verbal instructions provided, all the patients in the intervention group were supplied with written information on each of their prescribed medication (Appendix XIV). This contained information concerning the generic name (if applicable) for each medicine prescribed, the purpose, major side effects, the number of doses together with the time of the day correlating to patients' meals and any other important instructions. Normal discharge procedure was provided to the patients of the control group as in figure 4.2 which describes the usual care pathway for those discharged from St. Thomas' hospital (*i.e.*, the control group) compared to that for the intervention group.

On discharge, all the control and the intervention group patients were informed that the researcher would contact them to arrange a visit at their homes to 'check how they were coping with their medicines'.

Post hospital discharge, GPs for both intervention and control groups were sent a letter informing them about the nature of the study and asking for their permission to include their patients (Appendices XVa and XVb). GPs and community pharmacists for the intervention patients were also contacted by phone to inform them about the nature of the study, and then letters were send to them confirming participation of their patients in the study and to describe the study together with any information that may help them in identifying any changes to their patients' medications during their hospital stay (Appendix XVI). Three copies of the TTO (To Take Out) were issued for the intervention patients, one was sent to a community pharmacy of the patient's choice, if they failed to elect a particular pharmacy they were either excluded or considered as control patients. The second copy was given to the patient to keep or to show it to his/her GP before requesting further supplies of medication. Third copy was sent to the GP, together with a letter informing them that the patient has entered the study. Together with the TTO copies, blank forms of the written information sheet were sent to the community pharmacists to fill in with any modification in

the patient's regimen after leaving the hospital, which was to be handed to the patients when they/or their carers came to collect the prescription.

4.7.2 Phase II: Domiciliary Visit

The objective of this part was to follow-up patients discharged from the hospital into the community to observe whether their drug regimens have been changed, to investigate the information given to patients by healthcare professionals with respect to drugs and identify any medication-related problems and any other areas that needed to be improved. A further objective was to identify communication issues between healthcare professionals which could benefit the patient.

All patients were telephoned at home the day before a visit to confirm they were still willing to participate. At the home visit, each patient was interviewed in a standard manner using prepared questionnaires. The questionnaires were completed by the researcher to determine the following outcomes.

a. First Visit

The investigator visited the patients at home between 15 and 22 days after discharge from the hospital that is, after the initial supply of drugs provided by the hospital had ran out and a further supply obtained from the general practitioners. If applicable, any of patients' carers (including friends, relatives or neighbours) who helped with their medicines were invited to attend.

Assessment of Patient Compliance

Tablets counts were used as the sole instrument to calculate patient's adherence to their medication. Tablet counts as with most of the compliance measure instruments, have their drawbacks described in chapter 3, but the main drawback in this study is the fact that, patients might remove the tablets from other containers they kept at home, or they might adjust the number of tablets in the containers. Therefore, patients were not told before hand that their medication would be counted and were advised not to use any of the medication

they already had at their home. As the patients were visited at home, there was less chance for the patients to claim that they have forgotten or lost their medication.

Assessment of Patient's Knowledge and Quality of Life

During this visit, assessment of participants' knowledge of prescribed medicines was carried out using the questionnaire described in Section 2.3.4 as well as the quality of life using NHP instrument (Section 2.3.3).

During this knowledge assessment, patients of the intervention group were re-counselled again on their medication, and were informed about any changes to their medication initiated by their GPs after they left the hospital. They also were given the chance to ask any question and express and address any concern.

Wherever possible all medication held by the patient at the time of the visit was inspected, including those prescribed before hospital admission and those obtained from the general practitioner after discharge. The prescription issued on discharge and the medicines actually being taken by the patient at home after discharge were compared and if there were any discrepancies then GP was contacted (for intervention group only).

Assessment of Patient Satisfaction with the Information Provided

The previously (Section 2.3.6) described Satisfaction with the Medication Information Questionnaire (*SIMS*) was used to assess patient's satisfaction with the information provided to them during their hospital stay.

Monitoring Medication-Related Problems

Medication review was conducted for all the patients in both groups to identify any medication-related problems as described in section 2.3.7 including any interaction between medication. Patients were also asked about any problems they suffered from during the period of the study and were given the chance to describe any dissatisfaction with prescribed medication. Patients of the intervention group were informed about any problem observed and the best way to avoid these problems. GPs or community pharmacists were contacted by

the researchers concerning such problems and action taken as necessary for the patients in the intervention group.

b. Second Visit

The same outcomes were assessed (except patients' satisfaction with the information) as in the first home visit two months after hospital discharge.

4.8 Confidentiality and Ethical Issues

The confidentiality and anonymity of patient information was assured during the process of recruitment and during the home visits. Any potentially harmful MRPs identified during the homes visits were reported to the clinical pharmacist in St. Thomas' hospital. By the end of second domiciliary visit, the investigator discussed the potential problems that could cause harm in the control patients and were advised to review their medication with their GPs.

4.9 Monitoring Hospital Re-admissions

All the patients were monitored for the rate of the hospital readmissions at six months after hospital discharge. Patients' details stored on the hospital computer system were reviewed for the number of admissions and the reasons for the readmissions.

4.10 Assessment of the Reliability of Medication-Related Problem Classification System

The main supervisor was invited to assess the MRPs classification used in this study. A soft copy of case summaries were made and handed to the rater who was asked to code each problem according to the coding system described in section 2.3.7.2.

4.11 Quantitative Data Analytical Procedures

4.11.1 Data Entry and Handling

Before the data could be analysed, a case summary describing demographic data, compliance levels, knowledge score, NHP scores, *SIMS* score, and the different MRPs identified was made for each study subject. The data for the baseline interview, first and second visits was coded in accordance with a coding frame using SPSS. All the data was coded after completion of the two home visits for all study patients. The data was then transferred into

the SPSS, entered as groups of variables consisting of a number of measured attributes each describing a set of observations, being extracted from the different instruments, questionnaires and tools. Each variable represents one criterion to be analysed and each subject was entered as a case. Data was checked for errors during the process of data entry as cases by a second individual checking random pieces of entered data against the original case summary. Data checking was also carried out after data entry was completed. Missing data and blank cells were examined against the original data to identify any discrepancies. Also, randomly selected cases were then reviewed with the original data to check for any discrepancies.

Various statistics were used to summarize and describe the data set to meet the different objectives, *i.e.,* mean, median and mode. Standard Deviations (SDs) were used as an estimate of the data variability around the mean. To minimize type I error a p value equal to or less than 0.05 was taken as cut-off level for the level of significance. The smaller the p value the less the chance of rejecting the Null Hypothesis while it is true which would minimize any errors occurring by chance.

Different statistical tests being used to analyse data extracted from this study. These tests included:

4.11.2 Analysis of Frequency Tables

Pearson's Chi-squared (X^2) Test

The chi-squared (X^2) test for categorical data organizes two or more categorical variables in contingency table. This test is used to identify by how much the two observations differ and also whether this difference is more than might reasonably be expected to occur in sampling. To perform this test, the expected number in any group should not be less than 5 (if it is, two groups can frequently be pooled). The total number of observations should not be less than 20 and the test should be carried out on the actual numbers, not percentages (Altman, 1991).

4.11.3 Sample Distribution Tests

a. Two Independent Samples Analysis Tests

T-test for nominal continuous data was used to assess the probability of the samples having come from the same population. It is a parametric test that assumes the sample being analysed is from a population with specified normal distribution. The T-test can be used to compare two independent groups of observations. If the non-normal distribution was assumed the non-parametric Mann-Whitney U-test was used. It is a non-parametric alternative to the t-test for comparing data arose from two different groups of observations. It depends on ranking all the data from both observations as if they came from one sample.

b. Paired Samples Analysis Tests

A paired sample t-test was used to compare the observed mean difference of the data arising when the same individuals are studied more than once, usually in different circumstances *e.g.,* before and after. The Wilcoxon's signed rank test is the non-parametric equivalent, which uses both the magnitude and the direction of the changes in the data but not their actual values. Ranks are assigned to the differences between paired observations, regardless of whether the differences are positive or negative (Altman, 1991).

c. Reliability Measure and Degree of Agreement

The reliability of a measure refers to its reproducibility. One of the methods of assessing reliability is inter-rater reliability which depends on measuring the degree of agreement between different raters. By measuring the degree of agreement it is possible to compare the ratings of two observers for the same group of objects. The Kappa statistics is used to measure the extent of the agreement between the evaluations of different raters when each is rating the same sample, *i.e.,* inter-rater agreement. Kappa is based on two categorical variables arranged in contingency table and both categorical variables have to use the same category values in order to have the same number of categories. In the context of this study, the main supervisor (LG) who was completely unaware of the patient's allocation in the two groups coded each class of MRPs based on the data presented in the patient proforma by the researcher. The blinded rater coded the MRPs recorded on the proforma according to a predefined system of service-related or clinical-related problems. In addition, the rater

categorized the degree of the MRPs as mild, moderate or severe. It must be stressed that in the main, the nature of the MRPs was actually stated on the proforma as in most cases this could only be identified from a discussion with the patient. The process of coding by the second rater was performed independently for every patient for each home visit. The purpose of the second rater was simply to categorise types and severity of the problems. The rating performed by the main supervisor (LG) and the researcher (NMS) were compared for any agreement. The Kappa test was performed to specify the degree of agreement and compare the ability of the two raters to classify these problems. Values of Kappa have no absolute definitions but there are certain guidelines (Table 4.1) that can be used for interpretation of these values (Altman, 1991).

Table 4.1 Interpretations of the values of Kappa

Value of Kappa	**Strength of Agreement**
<0.2	Poor
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Good
0.81-1.00	Very Good

4.12 Computer software packages

The following computer software programmes were used to organize data in this study:

1. Microsoft Office Word XP, for word processing.
2. Microsoft Office Excel XP, for simple descriptive statistics and charting quantitative data.
3. Statistical Package for Social Science (SPSS), version 11 a package providing a range of simple and complex statistical procedures to analyse quantitative data.

This chapter ends the methodology section. The next two chapters will report the results and the discussions of the main research study. Data as collected using the different instruments will be analysed according to its nature whether categorical or numerical data and whether scores or percentages and represented as appropriate summary tables and figures. As described earlier in Chapter 3, different analytical procedures will be employed to conduct the comparison between the two groups. Data will be coded to be entered into the SPSS for further statistical analysis.

CHAPTER FIVE

RESULTS

CHAPTER FIVE
RESULTS

This chapter reports the results of the research study described in chapter four and is divided into eight main sections. The first section reports the patients' demographics. The second section presents time spent conducting the home visits and the counselling. Third to seventh sections represent the different outcomes assessed before and after the domiciliary visits. The last section describes the rate of hospital readmission for the recruited patients in a six-month period from the discharge date.

A comparison between the control and intervention groups has been made using a variety of statistical techniques. Student t-test, paired data t-tests and Mann-Whitney tests were used for group comparisons of interval/continuous data. Chi-squared and Wilcoxon tests were used to compare the distribution of patients with respect to categorical data. Kappa test was used for calculating the degree of agreements between different raters.

5.1 Recruitment and Patients Demographics

This section includes patients' demographic description of the patients recruited to the study.

5.1.1 Sample Recruitment

From the seven different wards visited by the investigator on a daily basis, 122 patients were recruited. Table 5.1 summarizes the number of patients recruited

Table 5.1 Total numbers of patients recruited to each group and numbers of patients who dropped out

Categories	Number of Patients (%)		
	Control	**Intervention**	**Both**
Recruited	61(50)	61(50)	122
Dropouts*	22(36)	21(34)	43(35)

* Dropouts refers to number of patients who failed to complete a second home visit

Due to the large number of patients who were approached daily by the investigator to participate in the study it was quite difficult to record all the patients who refused to take part in the study. Not to have strangers visiting the patients at home was main reasons given by the patients who refused to take part in the study.

Table 5.2 Numbers of patients who dropped out of the study as categorised by reason for dropout before first and second visits

Reasons of Dropping Out	Number of Patients					
	Before 1st visit			Before 2nd visit		
	Control	Intervention	Total	Control	Intervention	Total
Died	2	2	4	0	0	0
Hospital Readmission	6	5	11	8	7	15
Moved Outside London	2	2	4	0	1	1
Refused to Continue	1	2	3	1	1	2
Others*	1	0	1	1	1	2
Total	12	11	23	10	10	20

*The category *others* included unobtainable patients (researcher failed to re-communicate with the patients)

Twenty three patients (15 females) gave permissions to take part in the study but dropped out before the first assessment at home was conducted. Twelve were in the control group and the rest were from the intervention group. Out of the 122 recruited patients, 99 patients (49 in the control group) managed to complete the first assessment. Seventy nine patients completed both assessments (39 in the control group and 40 in the intervention group).

The reasons for refusing to continue participation in the study were either because of the length of the questionnaires or because the patients became confused after a while and forgot they had volunteered to take part. It is clear from table 5.2 that the two groups were quite similar in the dropout rate but it was difficult to carry out any statistical comparison between the numbers of patients dropping out during the study due to the low number involved.

5.1.2 Demographic data

This section reports the different demographic data for the patients in the two groups and the normality of distribution and any differences between the two groups at baseline just before

hospital discharge. Table 5.3, figures 5.1 and 5.2 show characteristics of the 122 recruited patients.

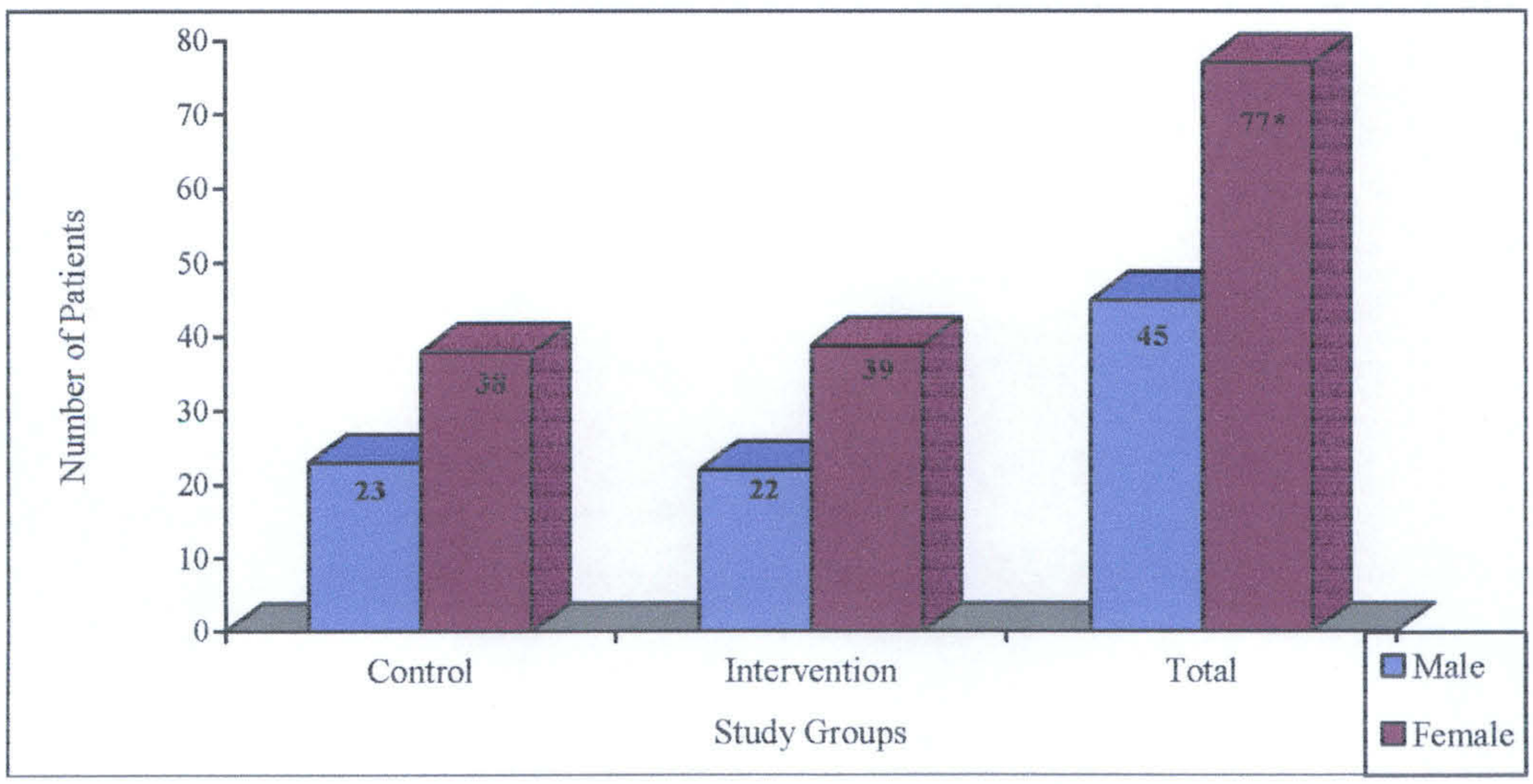
Table 5.3 Mean age (SD) and mean Mental Status Questionnaire Scores (SD) of patients recruited in each group*

Category	Control (SD)	Intervention (SD)
No. of Patients	61	61
Mean of Age in Years	77.0 (7.6)	79.4 (6.7)
Mean of Mental Status Questionnaire Score	23.4 (1.8)	23.8 (1.4)

* SD= Standard Deviation

The average age of the patients was 78.22 (SD=7.2) years, ranging from 65 years to 96 years (Median= 79 years). The distribution of ages over the two groups passed tests for normality. Patients' cognitive function was assessed during their hospital stay using the Mental Status Questionnaire (MSQ) described previously in Chapter 2. The mean scores for patients in each group are shown in table 5.3. There was no significant difference between the means of the (MSQ) scores between the patients of the two groups ($P<0.05$, two independent sample t-test).

Figure 5.1 Gender distributions of the intervention and the control groups



* Numbers on bars refer to the number of patients belong to each gender category in each group

When the patients were tested for their general sex distribution it was found that the sex distribution (Figure 5.1) as Male: Female for the control group was 1: 1.7 and the distribution for the intervention group was 1:1.8. The average age for the females was 79 (7.2) years and for males was 76.9 (7.1) years.

More than half (61%) of the patients were living alone while the rest were living with either families or friends. About 16% of the patients were receiving irregular help either by a member of the family, carer or district nurse. This help was limited to either filling dossette boxes, or arranging prescription and collection of medication.

Table 5.4 Frequencies and percents of the most commonly diagnosed medical problems

Disease	**Number of Patients (%)***		
	Control	**Interven**	**Both**
Cardiovascular	114(34.2)	130(40)	244(37.1)
Gastrointestinal	27(8.1)	32(9.8)	59(9.0)
Respiratory	26(7.8)	25(7.7)	51(7.8)
Infectious	34(10.2)	26(8)	60(9.1)
Musculoskeletal	24(7.2)	21(6.5)	45(6.8)
Central Nervous	10(3.0)	9(2.8)	19(2.9)
Endocrinological	23(6.9)	13(4)	36(5.5)
Fall	9(2.7)	10(3.1)	19(2.9)
Renal	10(3.0)	9(2.8)	19(2.9)
Anemia	10(3.0)	6(1.8)	16(2.4)
Miscellaneous	46(13.8)	44(13.5)	90 (13.7)
Total No. of Recruited Patients	61	61	122
Grant Total	**333**	**325**	**658**

*Column percent calculated by dividing the total number of patients in each disease category by the total number of patients in each study group.

Table 5.4 represents the numbers of patients with the different conditions as identified during their hospital stay, for which treatment was currently prescribed. Most of the patients suffered from more than one condition. Cardiovascular problems represented the highest percent of problems suffered by patients in both groups. More than half the numbers of the patients in the intervention group and about half of the control group patients were diagnosed

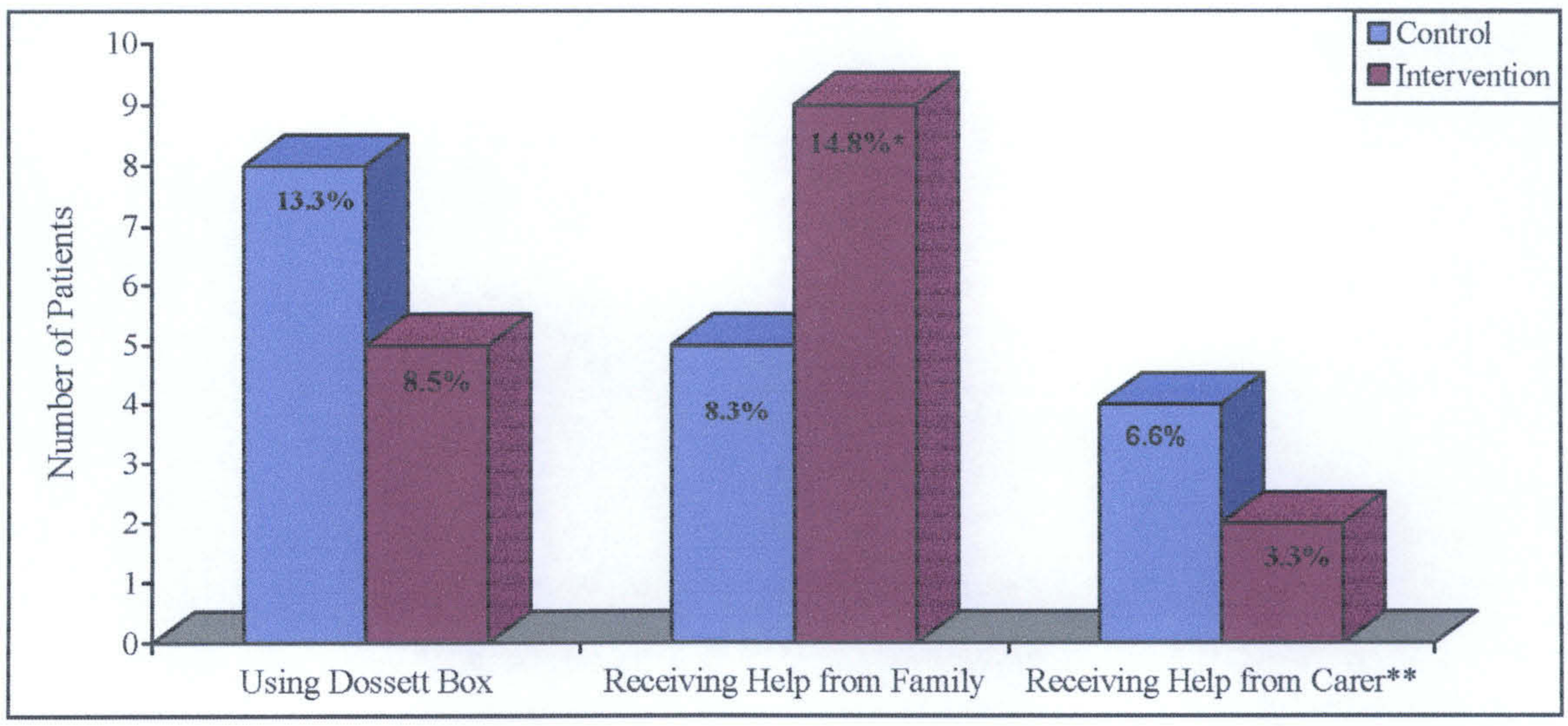
with hypertension followed by angina and myocardial infarction. Infections were the second most likely conditions elderly patients suffered specially the urinary tract and chest infections. Hiatus hernia and ulcers was presented equally in both groups. About one third of the patients had COPD and Asthma (for detailed data see Appendix XVIII).

Table 5.5 Length of hospital stay and number of medicines for both intervention and control groups

Characteristics	Control		Intervention	
	Mean (SD)	Range	Mean (SD)	Range
Hospital Stay (in Days)	15 (13.5)	1-82	15.7 (15.8)	2-110
No. of Medications Taken	8.3 (3.2)	3-20	7.4 (3.1)	2-17

The average length of the period the patients stayed in the hospital was 15.4 days ranging from 1-110 days. Patients were discharged from the hospital with total number of 909 medicines. Patients left the hospital with an average number of medications of 7.8 drugs/patient, ranging from 2 medicines to 20 medicines. The two groups were well matched with regard to the number of the medication between the two groups on discharge.

Figure 5.2 Numbers of patients in using compliance aids and help with medication from a carer or family



*Percent calculated by dividing the number of patients in each category by the total number of patients in each study group
** Carer either social carers or district nurses

When the patients were asked about the sources of help they could be receiving regarding their medication, it was found that 13 (10.9%) of the 122 recruited patients left the hospital with Dossett Box as a memory aid (Figure 5.2). About 17% of the total number of patients was receiving some help with their medication either through their families or through carers or nurses but not on a daily basis. No significant differences were observed between the two groups regarding the different types of helps.

Table 5.6 BNF Categories and frequencies of medication prescribed on discharge

Drug Category or Class	**Number of Medication (%)***		
	Control	**Interventio**	**Total**
Cardiovascular	176 (36.7)	196 (45.6)	372 (40.9)
Central Nervous	56 (11.7)	47 (10.9)	103 (11.3)
Gastrointestinal	58 (12.1)	49 (11.4)	107 (11.8)
Respiratory	72 (15.0)	61 (14.2)	133 (14.6)
Musculoskeletal	10 (2.1)	12 (2.8)	22 (2.4)
Topical Preparation	11 (2.3)	14 (3.3)	25 (2.8)
Endocrine	35 (7.3)	17 (4.0)	51 (5.6)
Obstetrics, Gynaecology and Urinary Tract	6 (1.3)	4 (0.9)	10 (1.1)
Miscellaneous	55 (11.5)	30 (7.0)	85 (9.4)
Total	**479**	**430**	**909**

*The percentage was calculated by dividing the numbers of medicines identified under each category by the total numbers of medications in each study group.

The 122 recruited patients reported using 909 dispensed medicines on discharge which were classified into ten major categories according to the British National Formulary (BNF). The number and type of each category is shown in table 5.6. Cardiovascular agents counted for the majority of the medications consumed by the participants; anticoagulants and antiplatelets and diuretics were prescribed most frequently. Respiratory medications especially steroid preparations were the second to be prescribed. Laxatives, PPIs and non-opioid analgesics represented more than 5% of the total prescribed medicines (for detailed data see Appendix XIX).

Table 5.7 Numbers and types of community pharmacy used

Category	Category (%)*		
	Control (n=59)	**Intervention (n=59)**	**Total (n=118)**
Number of Pharmacies Used			
One Pharmacy	49 (83.1)	51 (86.4)	100 (84.8)
>One Pharmacy	10 (17)	8 (13.6)	18 (15.3)
Type of Pharmacy			
Independent Pharmacy	43 (72.9)	40 (67.8)	83 (70.03)
Multiple Pharmacies	8 (13.6)	19 (32.0)	27 (22.9)
Unknown	8 (13.6)	0	8 (7.09)

*Column percent calculated by dividing number of patients in each category by total number of patients in each study group.

Table 5.7 describes the use of community pharmacies to collect prescribed medicines. Four patients in the control group said they definitely used more than one pharmacy and six said that they normally use one pharmacy but sometimes a second pharmacy can be used. For the intervention group, two of these always used more than one pharmacy and the rest said they sometimes used another pharmacy. Patients in the intervention group admitting using more than one pharmacy were asked to choose just one pharmacy for obtaining their medication during the period of the study.

5.2 Time Spent during counselling Sessions and the Home Visits

While patients of the intervention group received structured educational sessions on the discharge day, patients of the control group received the normal discharge procedures provided in the hospital, which may or may not include patient education by either the ward pharmacist or one of the nursing team. The time spent with each patient was recorded by the investigator from the moment the patient was approached till the end of session and this time varied according to the number of medications the patient was prescribed. The mean time spent in educating the intervention group patients was 23 (SD=12.57) minutes.

Out of the 122 patients 99 completed the first home visit and 79 patients completed the second home visit. The time of each home visit was reported to the nearest five minutes (Table 5.8).

Table 5.8 Time spent by investigator on domiciliary visits expressed as total number of hours Over whole study and the mean time (SD) in minutes spent with each subject

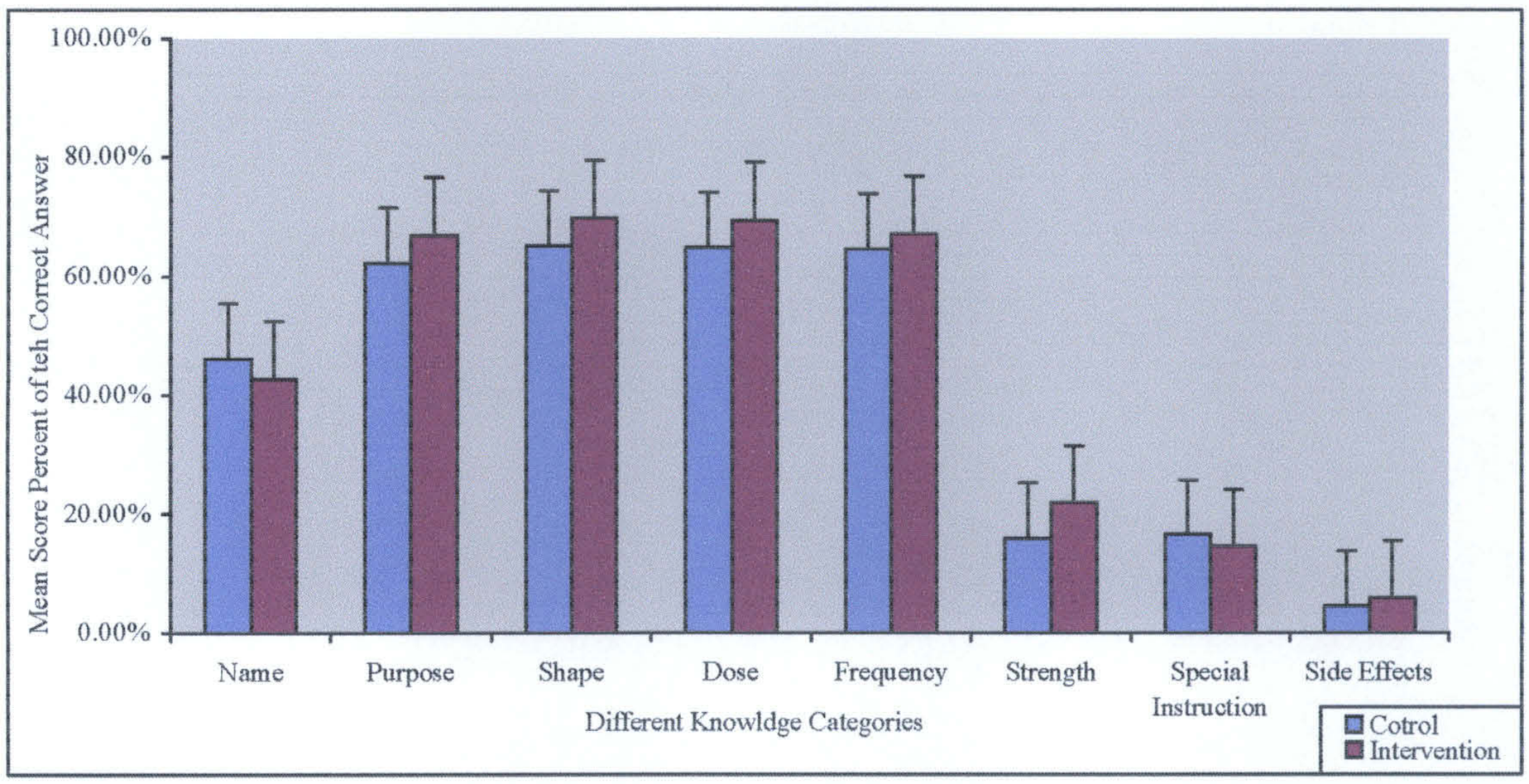
Time	Categories			
	1st Assessment		2nd Assessment	
	Control	Intervention	Control	Intervention
Total Time in Hours	38.8	34.5	21.8	22.8
Mean Time/Patient in Minutes (SD)	45.6 (15.3)	44.0 (16.1)	31.2 (11.5)	35 (15.5)

The total time spent conducting both the first and second home visits was about 118 hours; 73.25 hours for the first home visit, and about 45 hours for the second home visit. When the two groups were compared for the mean time spent with every patient during both the first and the second home visits, no significant differences were observed between the two groups at level of 95% during both visits (Two sample t-independent test, $P<0.05$).

5.3 Patients Knowledge Before and After Hospital Discharge

Patients were interviewed by the investigator to assess their level of knowledge. Patients were questioned about the name, purpose, shape, strength, dose, frequency, special instructions and the side effects of the medication on discharge and at each home visit. For the intervention group patients, this was performed before they were counselled. Patients were not allowed to refer to any written information to answer the questionnaires *e.g.*, labels.

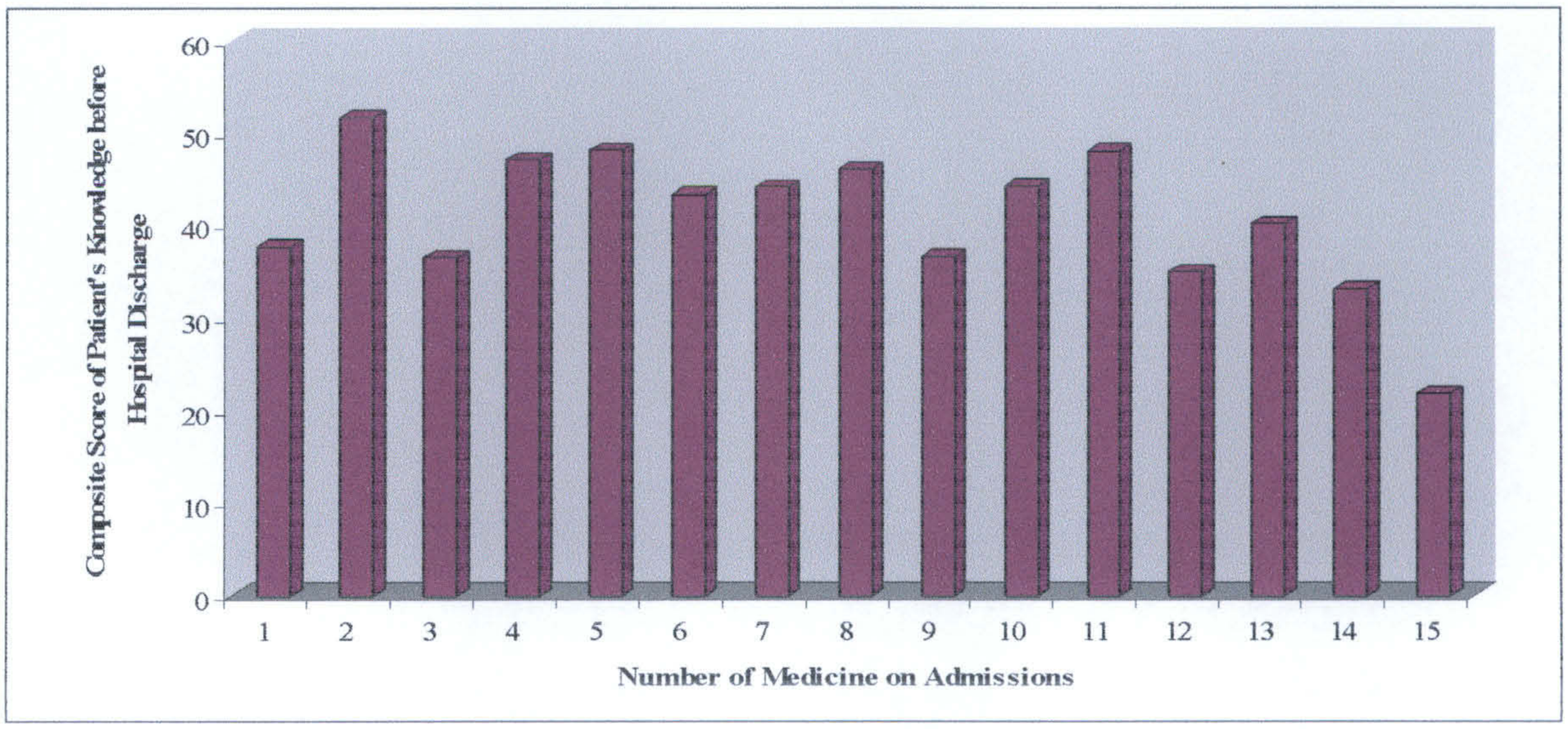
Figure 5.3 Patient medication knowledge scores assessed before hospital discharge*



*The scoring system for each question was calculated (as percentage) by dividing the correct answers (for the total number of medicines for each patient) by the theoretical required correct answers x 100.

Figure 5.3 describes the mean of the scores for medication knowledge for each of the eight questions before hospital discharge. The general knowledge of the patients about their medicines was high in both groups (more than 50%), except for the names, side effects, special instructions and the strength of the medication (For detailed data see Appendix XX).

Figure 5.4 Relationship between the number of medications on pre-discharge and the composite score of patient's knowledge



When the correlation between the total numbers of prescribed medication in both groups and the composite score of patient's knowledge was studied, it was found that there was no significant correlation between the two variables for both the control and the intervention groups (Spearman's Rank Test R= 0.08 and 0.18, P= 0.5 and 0.2 respectively).

The patient's knowledge questionnaire was administered during both first and second domiciliary visits to assess patients knowledge concerning their medication and the effect of the planned discharge counselling on patients knowledge levels.

Table 5.9 Mean knowledge score during both first and second home visits

Question	Mean Score %			
	First Home Visit		Second Home Visit	
	Control	Intervention	Control	Intervention
1. Name	44.7	64**	51.9	57.3
2. Purpose	69.8	83.4*	71.5	82.9
3. Shape	76.8	86.1*	77.4	87.8
4. Dose	79	88.9*	76.7	90.3*
5. Frequency	76.8	86.3*	71.5	86.8*
6. Strength	21.8	34.8	16.2	31.7
7. Special Instructions	16.4	33.8**	15.2	37.2**
8. Side Effects	3.1	11.5**	2.0	10.7**
Composite Score	**48.5**	**61.1**	**47.8**	**60.6**

*Statistically significant, Mann-Whitney U-test, $p<0.05$ between the two groups at each home visit
**Statistically significant, Mann-Whitney U-test, $p<0.001$ between the two group at each home visit

As mentioned previously, there were no significant differences between any of the patient's knowledge criteria before discharge (Figure 5.3). Table 5.8 shows the percentage of means of the knowledge score as assessed by patient interview.

When the study subjects of the two groups were compared for the level of knowledge, it was found that there were significant differences (Table 5.9) between the two groups for all the questions except the knowledge concerning the drug strength during the first assessment, while during the second home visit, significant differences (patients of the intervention group showed better results) were shown for questions numbers from 4, 5, 7 and 8.

Within the group, the improvement in all the knowledge aspects reached level of significance for the patients in the intervention group two weeks (1st assessment) after their hospital discharge ($P<0.001$, Wilcoxon Signed-rank test for questions 1, 2, 5,6 and 7, and $P<0.01$, Wilcoxon Signed-rank test for the remaining three questions3, 4 and 8).

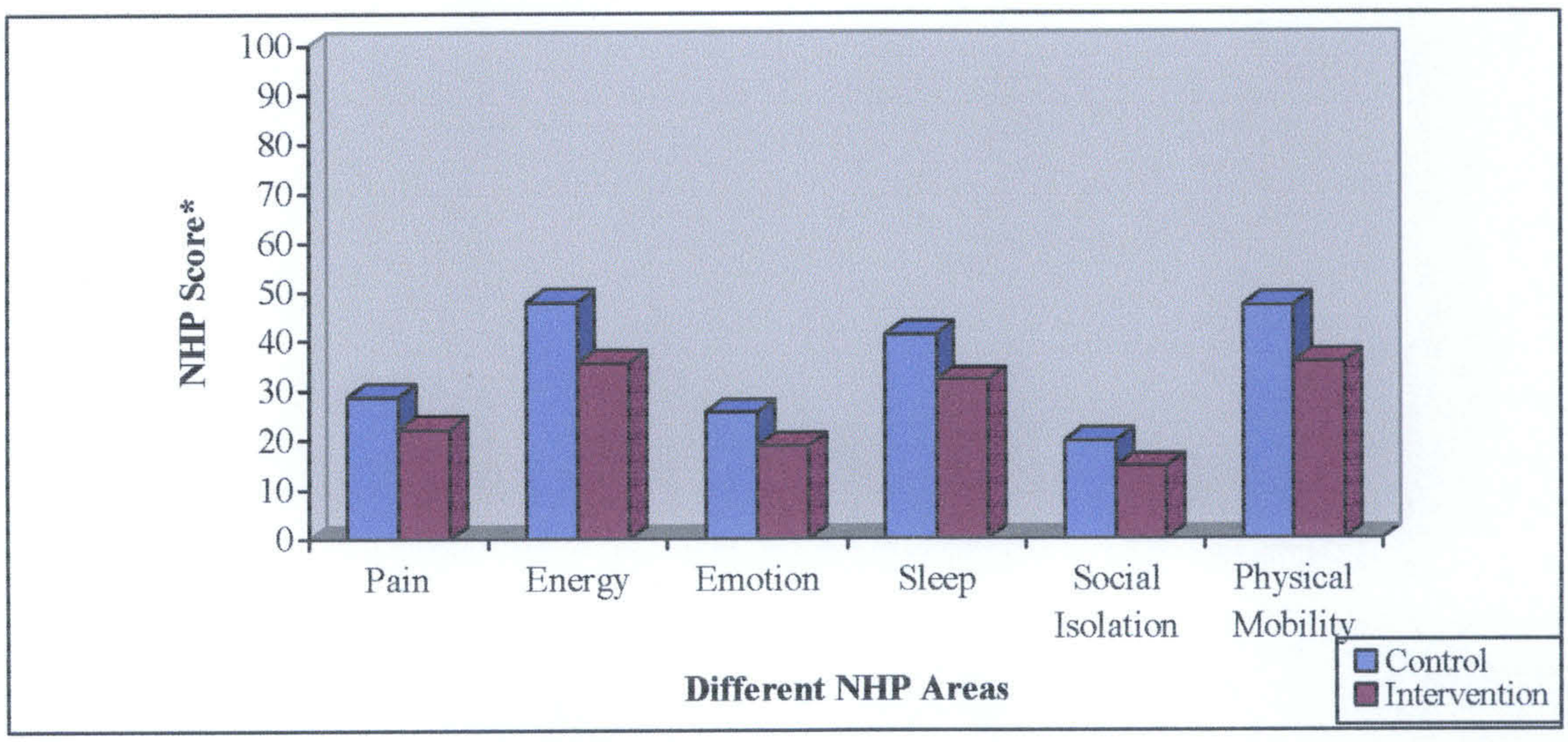
Improvement in patient's knowledge was observed and reached level of significance for the control group for questions 3, 5 ($P<0.01$, Wilcoxon Signed-rank test) and questions 4, 6 ($P<0.05$, Wilcoxon Signed-rank test) during the first assessment. When the change was calculated while moving from the first home visit to the second home visit for patients in both groups, an improvement in intervention patients' knowledge concerning medicine shape, dose, time of administration and the special instructions was observed but these improvements did not reach any level of significance. Patients in the control group showed decline in their knowledge concerning medicine strength, dose, time, special instructions and side effects during the second assessment. This decline was statistically non-significant except for drug strength (question 4) and drug frequency (question 6) (Wilcoxon Signed-rank test $P=0.01$ for booth criteria).

The total score was calculated by summation of the score of the eight questions for every patient and calculating the mean percent for the total number of patients in each group during each assessment. This score was significantly higher for the intervention group during both first and second visits ($P<0.001$, Mann-Whitney U-test). The improvement of the total score reached significance for both control and intervention groups on the first assessment (Wilcoxon signed-rank test, $P= 0.007$ and $P=0.000$ respectively). The control group showed significant decline in the composite score during the second assessment (Wilcoxon signed-rank test, $P= 0.03$).

5.4 Quality of Life and Nottingham Health Profile Before and After Hospital Discharge

As mentioned previously (Chapter 4), patients' quality of life was measured using the Nottingham Health Profile questionnaire which was administered before and after hospital discharge.

Figure 5.5 Nottingham Health Profile administered to both the control and the intervention groups before hospital discharge



*The maximum score for each of the areas covered by the Nottingham Health Profile is 100. The lower the score the "better" the status in each category

There was no significant difference (Figure 5.5) between the control group and the intervention group in any of the criteria of the NHP ($P<0.05$, Mann-Whitney U-test), except for the physical mobility (Mann-Whitney U-test and $P=0.005$) and energy (Mann-Whitney U-test and $P=0.038$) criteria where a higher score was achieved by the control group (for detailed data see Appendix XXI).

The Nottingham health profile was re-administered during the domiciliary visits to study the changes quality of life post hospital discharge.

Table 5.10 Nottingham Health Profile administered to both the control and the intervention groups on the first and the second home visits

Area	Mean Score % (SD)			
	1st Assessment		2nd Assessment	
	Control	Intervention	Control	Interventio
Pain	35.0(30.2)	21.5(30.1)*	28.4(26.3)	20.2(24.5)
Energy	56.9(39.8)	36.8(39.1)*	40.6(38.2)	34.7(36.1)
Emotion	25.0(27.1)	16(21.3)	24.7(27.0)	16.3(21.7)
Sleep	38.6(34.6)	19.9(26.4)**	28.2(27.9)	20.2(26.2)
Social Isolation	38.4(138)	10.6(19.9)*	28.2(28.7)	20.2(19.4)
Physical Mobility	47.4(22.3)	30.8(27.4)**	41.7(23.9)	31.2(29.1)

*Statistically significant, Mann-Whitney U-test, $p<0.05$ between the two groups at each home visit
**Statistically significant, Mann-Whitney U-test, $p<0.01$ between the two group at each home visit

When the patients in both groups were compared for any difference between the areas of the NHP during the first domiciliary visit, significant differences were observed (intervention patients showed lower score, *i.e.,* better quality) for all the tested criteria except emotion, therefore showing better quality of life post hospital discharge. No significant difference was observed between the two groups during the second home visit.

Friedman test was used to study any changes in the Nottingham Health Profile scores for either baseline, first or second assessments at a level of 95%. It was observed that there was a significant difference between the points of assessments for the patients of the intervention group regarding the area of sleep. The Wilcoxon sign rank test ($P<0.05$) was used to identify the position of this difference. It was found that the significant difference was observed during the fist assessment *i.e.,* there was a significant improvement in the sleep pattern for the patients of the intervention group immediately after leaving the hospital.

5.5 Patient's Compliance

Patient's adherence to their medication was measured whenever possible using tablet counts. Compliance could not be measured for topical preparations, liquids, inhalers, eye-drops, medicines taken on "when required" basis and for antibiotic courses which had been completed before the visit, unless the patient admitted to non-compliance.

Percent adherence was calculated by determining the number of tablets that should have been taken in the interval between hospital discharge and the first home visit after two weeks (first assessment) and that between the first and the second home visits after four weeks (second assessment). The numbers of tablets that were actually taken between the intervals were then divided by what should have been taken theoretically multiplied by 100.

Table 5.11 Compliance (Mean Score Percent) as estimated by tablet counts on first and second home visits*

Compliance %	Categories			
	1st Assessment		2nd Assessment	
	Control	Intervention	Control	Intervention
No. of Patients	40	45	37	37
Mean Score % (SD)	75.6 (26.4)	85.7 (21.1)	73.3 (28.3)	90.6 (11.9)

*The average adherence score percent for all drugs was calculated by summing percent adherence for all drugs and dividing by the total number of drugs the person was taking X 100

A number of tablet counts were missing owing to non-availability of tablets to perform an assessment at the time of the visit. Assessment of compliance during the first visit was impractical for a number of the patients. The main reason for this was that some were using their old stock of medication they kept at home before their hospital admission. Other patients mixed their tablets (from the hospital and the community pharmacy) together in one container, one patient kept some of his medication at his daughter's home.

Compliance for patients using dossette boxes was calculated and included within the compliance calculated for patients without these aides. Compliance was considered to be 100% for patients using memory aids *e.g.,* Dossett boxes and where the correct number appeared to have them removed at the time of the visit.

The two groups were compared for the level of compliance at the first and second home visits (Table 5.11). The intervention group had a higher compliance score compared to the control group two weeks post hospital discharge. The total score of compliance was significantly higher for the intervention group than the control group during the second assessment ($P<0.05$, two sample t- independent test).

There was a slight significant improvement in the compliance level for the counselled patients while moving from the first to the second home visit (P<0.05, T-test for paired sample). Patients of the control group showed a decrease in the compliance score during the second assessment but this decline was statistically non significant (P<0.05, T-test for paired sample).

*Table 5.12 Compliance level described as numbers of subjects (%)*falling into one of three different descriptive categories*

Compliance Categories	Number of Patients (%)			
	1st Assessment		2nd Assessment	
	Control	Intervention	Control	Intervention
Total No. of Patients	40	45	37	37
Underuse	15 (37.5)	7 (15.6)	14 (37.8)	8 (21.6)
Compliant	22 (55.0)	33 (73.3)	17 (46.0)	29 (78.4)
Overuse	3 (7.5)	5 (11.1)	6 (16.2)	0 (0)

*Column percent calculated by dividing the total number of patients in each compliance category by the total number of patients in each study group

Patients' behaviour towards their medication was classified into three categories. Table 5.12 describes the different compliance categories assessed by tablet count as follows: a) *underuse* -<85% *compliance*, b) *overuse*-115% compliance and c) *Compliant*- 85-115% compliance. The deviation of 15% (100+/-15%) was used in accordance to that used in other studies (Wood *et al.*, 1992) and (Eagleton *et al.*, 1993).

For the first assessment, there were higher numbers of compliant patients in the intervention group than those in the control group. Intervention patients who were classified to be underusing their medication were less than half the number of the same category in the control patients during the first assessment.

It was difficult to carry out any statistical comparison between the two groups during the second visit on the level of the overuse alone (cell had zero value), so over and underuse categories were combined to form non-compliant class and a comparison was recalculated between the intervention group and the control group on the basis of compliers or non

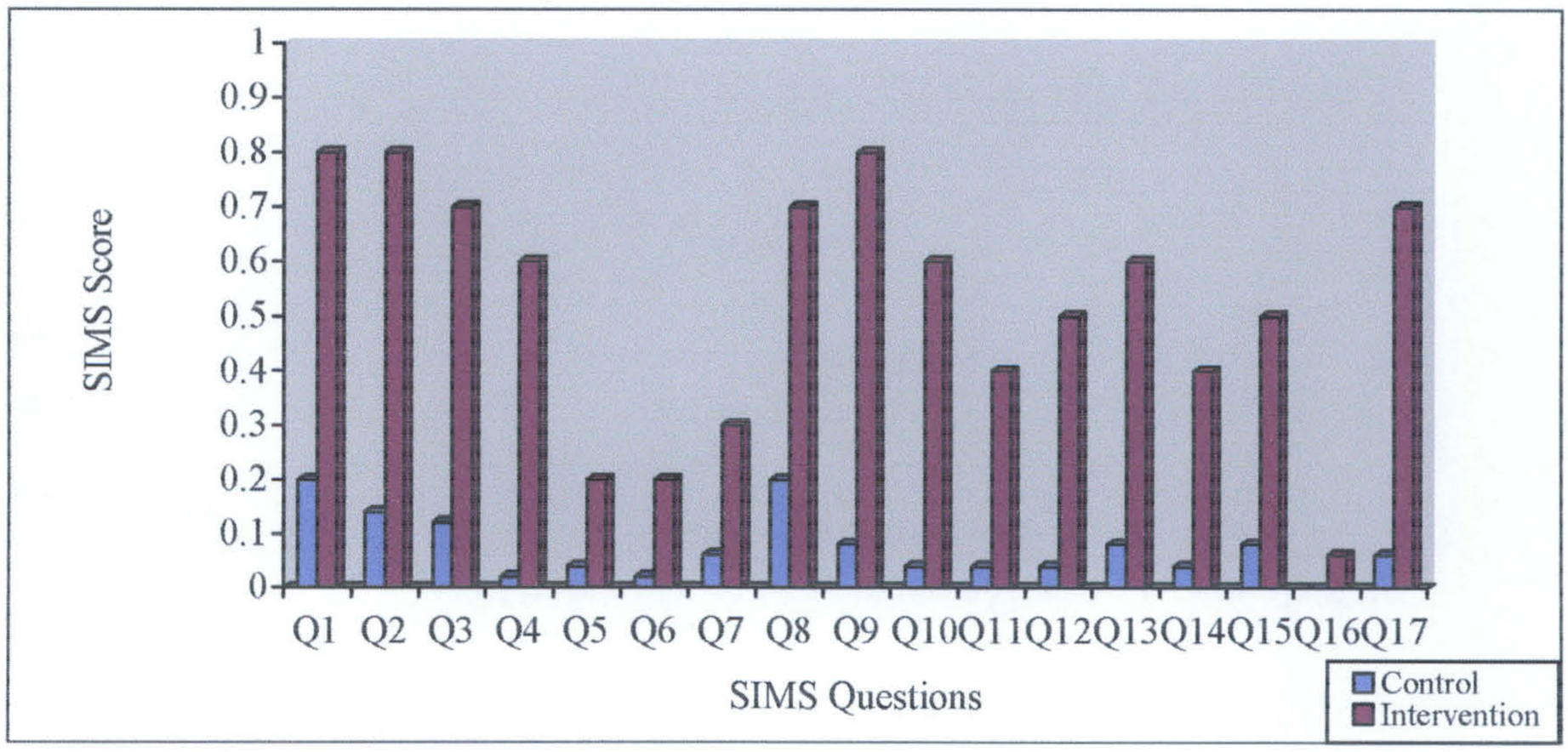
compliers. 78% of the intervention group patients were described to be compliers in comparison to only 55% of the control group. A significant difference was obtained on these basis during the second assessment (Chi squared test, DF=1 and P=0.004).

5.6 Patient Satisfaction with Information

The *SIMS* questionnaire was used to assess patients' satisfaction with the information they received during their hospital stay. This questionnaire was administered to the patients during the first home visit. Patients who did not remember if they have been counselled were given a score of zero.

Results shown in figure 5.6 suggested that in general, there was higher level of satisfaction with the medicine information provided to the patients of the intervention groups in comparison with those of the control group. The total score was calculated regarding satisfaction with information received for all medication. Patients of both groups were mostly satisfied regarding the medicine name, purpose and how to use the medicine.

Figure 5.6 Patient satisfaction with the information provided measured by the SIMS questionnaire during the first home visit*



*See Appendix V for questions from 1 to 17

Patients of the intervention group were satisfied about the previously mention areas together with the information concerning obtaining further supply and the action needed to be taken in case a dose was forgotten. There was a significant difference between the two groups in the scores of all the questions except question number 16 ($P<0.05$ Mann Whitney U-test).

5.7 Identification and Classification of Medication-Related Problems

During the home visits, patient's medication was reviewed by the investigator to identify and classify medication-related problems (for the patients in the intervention group) and resolve them wherever possible. Also the patients were given the opportunity to express their concerns regarding their medication regimen.

An initial assessment was made by the investigator regarding the MRPs identified. The problems were categorized into 16 different classes:

- Therapeutic failure
- Side Effects
- Drug interaction
- Contraindication
- Interface issues
- Dosage problems
- Knowledge problems
- Compliance problems
- Running out of medication
- Stopping of necessary medication
- Repeating stopped medication
- Duplication of medication
- Using unnecessary medication
- Storage problems
- Physical problems
- Others

The category ***others*** included the usage of expired medication, difficulties in reading labels or label mistakes.

A total of 226 medication-related problems were identified in both groups (101 problems assigned to the intervention group) at the first home visit with a mean of 2.3 (S.D= 1.56) MRPs/patient. More than half of these problems were assigned to the patients of the control group. This total decreased to 152 problems (55 problems identified in the intervention group) during the second visit with a mean of 1.92 (S.D= 1.25) MRPs/patients. When the percent of the total number of MRPs identified in the intervention group was calculated it was found that, the percent of the medication-related problems for the intervention group (101/226 x 100) decreased from 45% during the first home visit to 36% during the second visit. There was an observed but non-significant difference between the two groups regarding the mean of MRPs during the first home visit but a significant difference was observed during the second visit (Mann Whitney U-test, P= 0.001). It was difficult to carry out further

statistical analysis on the individual categories as the number of observations in each cell was very small. To analyse more precisely the true effect of programme of subcategories of MRPs, the data was reclassified and analysed using the validate PCNE system described in section 2.7.

5.7.1 PCNE Classification System

As described in chapter 2, the PCNE system was chosen as a classification system in this study because of its ability to identify the clinically related MRPs and relate them to causes and interventions performed, *i.e.*, the system uses three classes; problems, causes and interventions. Each category has different basic domains; six primary domains for problems, six primary domains for causes and four primary domains for interventions. Each problem reported was coded separately; more than one cause or interventions can be correlated to each problem.

5.7.1.1. Classification of the Problems Identified

Problems were classified under the main six domains and these six domains were re-categorized again into 17 different problems (Appendix VI). The percent, calculated by dividing the number of problems identified in each category by the total number of problems identified in each study group, of the identified problems in each category was calculated to make the process of comparison easier.

Table 5.13 Classification of the number of the MRPs between the control and the intervention groups (according to PCNE)

Category	Number of Problems (%)			
	1st Visit		2nd Visit	
	Control (n=49)	Intervention (n=50)	Control (n=39)	Intervention (n=40)
Side effect	21 (15.7)	24 (22.6)	11 (10.8)	15 (24.6)
Inappropriate drug or form (not most appropriate for indication)	3 (2.2)	2 (1.9)	3 (2.9)	2 (3.3)
Inappropriate duplication of therapeutic group or ingredient	1(0.7)	3 (2.8)	2 (2.0)	1 (1.6)
Contra-indication for drug	5 (3.7)	2 (1.9)	2(2.0)	2 (3.3)
No clear indication for drug use	2 (1.5)	0 (0)	2 (2.0)	0 (0)
No drug prescribed but clear indication	8 (6.0)	4 (3.8)	3 (2.9)	0 (0)
Drug dose too low or regimen not frequent enough	12 (9.0)	10 (9.4)	13 (12.7)	8 (13.1)
Drug dose too high or dosage regimen too frequent	6 (4.5)	5 (4.7)	7 (6.9)	2 (3.3)
Drug not taken/administered at all	20 (14.9)	12 (11.3)	10 (9.8)	11 (18)
Wrong drug taken/administered	12 (9.0)	6 (5.7)	9 (8.8)	5 (8.2)
Potential interaction	2 (1.5)	4 (3.8)	2 (2.0)	2 (3.3)
Patient dissatisfied despite taking drugs correctly	7 (5.2)	8 (7.5)	7 (6.9)	4 (6.6)
Insufficient awareness of health and disease	25 (18.7)	18 (17.0)	19 (18.6)	4 (6.6)
Unclear complaints, clarification necessary	6 (4.5)	7 (6.6)	7 (6.9)	4 (6.6)
Therapy failure for unknown reason	4 (3.0)	1 (0.9)	5 (4.9)	1 (1.6)
Total Number of Problems	**134**	**106**	**102**	**61**

*Column percent calculated by dividing the number of problems in each category by the total number of problems of all the categories in each study group X 100.

Table 5.13 shows the distribution of the different numbers of MRPs among the patients of both the control and the intervention groups at the two domiciliary visits. Some of the problems could not be classified under any of the specified problem categories (*e.g.*, storage problems and using out of date medication) those problems were classified under "*unclear complaints, clarification necessary*".

A total of 240 problems were reported during the fist home visit, 134 (56%) were assigned for the control group. The percentage of the identified MRPs in the control group increased to 63% (102/163) during the second home visit. Intervention group patients had 106 problems (44%) during the first home visit and this number went down to 61 problems (37%) during the second home visit. The average numbers of problems identified in both the intervention and the control groups during the first home visit were 2.1 and 2.7 problems/patient respectively. This value was almost the same (2.6problems/patient) for the control group, but decreased to 1.5 problems/patient for the intervention group during the second assessment.

Side effects were the main problem (19%) patients suffer during the first home visit followed by insufficient awareness of the health and disease (18%). The opposite was true for the control group during the same domiciliary visit. Side effect kept the same main problem intervention group suffered during the second visit. The main contribution to the difference observed during the second home visit appears to be "insufficient awareness of health and disease" for the control group.

The total number of identified problems was significantly lower for the intervention group during the second home visit (Chi-squared test, DF=1 and P=0.03) but there was no difference between the two groups at the second domiciliary visit (Chi-squared test, DF=1 and P=0.18). Numbers of problems in individual category were too low for performing any statistical analysis.

The problems identified had all arisen since discharge. Inappropriate drugs or regimens all related to the taking of medication not on the discharge list *e.g.*, taking of old stock, interface issues concerning GPs prescribing and new prescriptions issued by the GPs. Similarly interaction/contraindications occurred due to problems with non-discharge medicines. Other problems such as side effects are related to both discharge and other medication taken at home.

Because one patient may suffer form more than one MRP for the same drug, the numbers of patients experiencing different problems were investigated according to the PCNE system and the results are shown in Appendix XXII. Overall, the incidence follows the same pattern as was obtained from table 5.13.

Table 5.14 Numbers of problems in each MRPs domain identified in the patients of the two groups (according to PCNE)

Category	Number of Problems (%)					
	1st Visit			2nd Visit		
	Control	Intervention	Total	Control	Intervention	Total
P1. Adverse reaction(s)	21(15.7)	24(22.6)	45(18.8)	11(10.8)	15(24.6)	26(16.0)
P2. Drug choice problem(s)	19(14.2)	11(10.4)	30(12.5)	12(11.8)	5(8.2)	17(10.4)
P3. Dosing problem(s)	18(13.4)	15(14.2)	33(13.8)	20(19.6)	10(16.4)*	30(18.4)
P4. Drug use/administration	32(23.8)	18(17.0)	50(20.8)	19(18.6)	16(26.2)	35(21.5)
P5. Interaction(s)	2(1.5)	4(3.8)	6(2.5)	2(2.0)	2(3.3)	4(2.5)
P6. Others	42(31.3)	34(32.1)	76(31.7)	38(37.3)	13(21.3)	51(31.3)
P7 (P5+P6)	44(32.8)	38(35.8)*	82(34.2)	40(39.2)	15(24.6)**	55(33.7)

*Statistical Significant at p<0.05, Chi-squared test
**Statistical Significant at p<0.01, Chi-Squared test

According to the PCNE classification system, each group of identified problems is a subclass of one of six major domains (Table 5.14). Category domain (P6) ***Others*** was the main domain patients of both groups experienced during both the first and the second home visits. "*Drug interaction*" problems (P5) was the least frequent problem during both assessments for both the intervention and the control groups. More patients from the control group suffered from "*drug choice and dug use/administration*" problems than the patients of the intervention groups during the first assessment. The numbers of patients in the control group suffering from the "*dosing problems*" and "*others*" was almost double the number in the intervention group during the second home visit. Although there was a small increment (5%) in the number of the "*dosing problems*" in the patients of the control group while moving from the first to the second domiciliary visit, this increment was statistically significant (Wilcoxon Signed-rank test, P> 0.05).

The Chi-squared test was used to compare the difference between the number of problems in the control and the intervention with regard to each domain during each assessment. Because problem domains P5 has cells with expected counts less than five, a new problem domain category (P7) was created by combing P5 and P6 together.

During the second home visit, the number of the problems in the dosing problem domain for the control group were significantly higher than those of the intervention group (Chi-squared test, P= 0.02, DF=1). Adverse drug reactions were experienced by more patients in the intervention group than the control group during the two home visits.

When P5 and P6 were combined together forming P7, a significant difference was observed between the control and the intervention groups during both the first (Chi squared test, P= 0.04, DF=1) and the second assessments (Chi squared test, P=0.003, DF=1) *i.e.*, patients of the control group had more problems than those in the intervention group during both home visits.

5.7.1.2 Classification of the Causes for the Identified Problems

Identified problems had 24 different causes to be correlated and these 24 causes are re-categorized again under 6 main cause domains.

Table 5.15 Classification of the different causes of the MRPs between the control and the intervention groups (according to PCNE)

Category	Number of causes (%)*			
	1st Visit		2nd Visit	
	Control	Intervention	Control	Intervention
Inappropriate drug selection	8(4.3)	4(3.5)	4(2.7)	3(6.2)
Inappropriate dosage selection	2(1.4)	3(3.5)	3(2.7)	1(1.5)
Pharmacokinetic problem	4(3.)	5(3.5)	2(2.7)	3(4.6)
Synergistic/preventive drug required	4(3.6)	2(2.6)	4(2.7)	1(0)
Deterioration/improvement of symptoms	2(1.4)	1(0.9)	4(3.6)	2(3.1)
Manifest side-effect, no other cause	20(14.3)	24(20.7)	7(6.4)	13(2.0)
New symptom or indication revealed/presented	0(0)	0(0)	0(0)	1(1.5)
Drug underused/ under-administered	8(6.4)	4(2.6)	8(5.5)	6(9.2)
Drug overused/over-administered	5(5.0)	3(2.6)	7(10.0)	2(3.1)
Therapeutic drug monitoring required	0(0)	3(2.6)	0(0)	1(1.5)
Drug abused	1(0.7)	0(0.9)	2(1.8)	0(0)
Patient unable to use drug/form as requested	10(7.1)	3(3.5)	7(5.5)	2(6.2)
Instructions for use/taking unknown	21(13.6)	12(11.2)	13(12.7)	2(3.1)
Patient unaware of reason for drug	8(3.6)	5(4.3)	7(4.6)	1(3.1)
Lack of communication between health professionals	14(12.1)	7(5.2)	9(10.9)	3(6.2)
Patient has difficulties reading/understanding PIL**	0(0)	2(2.6)	1(0)	1(0)
Patient forgets to use/take drug	7 (5.0)	10(6.9)	6 (7.3)	7 (9.2)

*Column percents were calculated by dividing the number of causes in each cause category by the total number of causes in each study group X 100.
**Patient Information Leaflets.

Table 5.15 continued classification of the different causes of the MRPs between the control and the intervention groups (according to PCNE)

Category	Number of Causes (%)			
	1st Visit		2nd Visit	
	Control	Intervention	Control	Intervention
Patient has concerns with drugs	2 (1.4)	8 (6.9)	3 (2.7)	3 (4.6)
Patient suspects side-effects	3 (2.1)	3 (2.6)	3 (2.7)	1 (1.5)
Burden of therapy	0 (0)	0 (0)	0 (0)	2 (3.1)
Prescribing error (slip of pen)	1 (0)	1 (2.6)	0 (0)	1 (0)
Dispensing error	4 (2.9)	4 (3.5)	7 (6.4)	4 (6.2)
Other reason	3 (2.1)	4 (3.5)	2 (0.9)	2 (3.1)
No obvious reason	15 (9.3)	5 (4.3)	9 (8.2)	1 (3.1)
Total No. of Causes	**142**	**113**	**108**	**63**
Total No. of Problems	**134**	**106**	**102**	**61**

Table 5.15 shows the distribution of the number of the causes for the different MRPs within the control and the intervention groups during the two home visits as classified by the PCNE system. More than one cause can be assigned for each problem. There were a total of 255 causes reported during the first home visit (average of 1.06causes/problem). The main cause for the MRPs identified during the first home visit was the "*manifested side-effects*" (17.5%) for both the control and the intervention groups. This was followed by "*unknown instructions of use and/or administration of the medication*". "*Lack of communication between health professionals*" was the third common cause in the control group during the first home visit.

During the second home visit, 171 causes were attributed to the MRPs with an average of 1.05 causes/problem. The "*lack of instructions of how to use medication*" was the main cause of the MRPs among the control group followed by "*lack of communication between the healthcare professionals*". Patient education and liaison with the primary healthcare professionals managed to overcome many problems in the intervention group. Drug underuse and the forgetting to take medication were the second two causes for MRPs after manifested side effects. A non-significant difference was observed for the total number of the causes between the control and the intervention groups during the first home visit *i.e.*, the number of causes were higher in the control group compared to the intervention. A statistically

significant difference was observed between the two groups during the second visit (Chi-squared test, DF= 3, and P= 0.001).

The number of causes as classified by the PCNE system decreased dramatically between the first and the second home visits for the patients in the intervention group, and this change was proven to be statistically significant (Wilcoxon Signed-rank test, P= 0.000) and this was expected as the total number of problems decreased as well from the first to second assessment. There was an increase in the percent of the causes for the control group from the first assessment to the second assessment.

Table 5.16 Number of different causes domains for the different MRPs identified in both groups during both home visits (according to PCNE)

Category	Number of Causes (%)*			
	1st Visit		2nd Visit	
	Control	Intervention	Control	Intervention
C1. Drug/dose selection(s)	40(28.2)	39(34.5)	24(22.2)	24(38.1)
C2. Drug use process	24(16.9)	13(11.5)	24(22.2)	11(17.5)
C3. Lack of/or wrong information	43(30.3)	26(23.0)**	30(27.8)	7(11.1)***
C4. Patients/psychological related	12(8.5)	21(18.6)	12(11.1)	13(20.6)
C5. Logistics of drug supply	5(3.5)	5(4.4)	7(6.5)	5(7.9)
C6. Others	18(12.7)	9(8.0)	11(10.2)	3(4.8)
No. of Patient	**49**	**50**	**39**	**40**
Total No. of Cause Domains	**142**	**113**	**108**	**63**

*Column percent was calculated by dividing the number of causes in each cause domain category by the total number of causes in each study group X 100.
** Statistical Significant at p<0.05, Chi-squared test.
*** Statistical Significant at p<0.001, Chi-squared test.

When the two groups were compared for any change in the number of cause domains (Table 5.16) during both visits, a significant difference was only observed for "*the lack or wrong information*", where the problems caused by "*lack of information*" in the control group were higher than those in the intervention group during both home visits.

The percent of the domain C3 "*the lack or wrong information*" decreased to almost the half for patients in the intervention group while moving from the first (23%) to the second home visit (12%). This decrease was proven to be statistically significant (Wilcoxon Signed-rank test, P= 0.001). For the patients in the control group, there was a significant increase in the number of causes of the fifth "*logistics of the drug supply*" domain between the first and the second assessment (Wilcoxon Signed-rank test, P= 0.03).

5.7.1.3 Classification of Interventions Performed

Interventions performed can be classified under one of ten different intervention classes, and these ten classes can be combined under four main domains according to the level of the intervention.

Table 5.17 Classification of different interventions after hospital discharge (according to PCNE) for the intervention group

Category	**Number of Interventions (%)***	
	1st Visit (n= 50)	**2nd Visit (n=40)**
Prescriber informed only	19 (19.6)	2 (7.7)
Prescriber asked for information	4 (4.1)	2 (7.7)
Intervention proposed, approved by prescriber	4 (4.1)	0
Patient medication counselling	62 (63.9)	21 (80.8)
Spoken to family member/caregiver	4 (4.1)	0
Dosage Changed	1 (1.0)	0
Other interventions	3 (3.0)	1(3.8)
Total No. of Interventions	**97**	**26**

*Column percent calculated by dividing the numbers of interventions in each intervention category in the study group by the total numbers of interventions during each visit X 100%

Most of the interventions performed (Table 5.17) during both the first and the second home visits were either "*the patient medication counselling*" or "*informing the prescriber*" about the medication-related problems and then the category ***others***.

Table 5.18 Classification of the different intervention according to the intervention domains (according to PCNE)

Category	Number of Interventions (%)*	
	1st Visit	2nd Visit
I1. At prescriber level	27(27.8)	4(15.4)
I2. At patient (or relative) level	66(68)	21(80.8)
I3. At drug level	1(1.0)	0
I4. Others	3(6.1)	1(3.8)
No. of Patient	**50**	**40**
Total No. of Interventions	**97**	**26**

*Column percent calculated by dividing the numbers of interventions in each intervention domain in the study group by the total numbers of interventions during each visit X 100%.

Interventions were performed during the first home visit mainly to overcome two major problems; knowledge and interface issues. Interventions at the patient (or carer) level were the highest compared to the others during both first and second home visits (Table 5.18). The main intervention at the prescriber level was "informing the prescriber" about the changes to the patients' medication during their hospital stay to overcome any interface problems and resulting from discrepancies between the medication prescribed on discharge and those being prescribed post discharge.

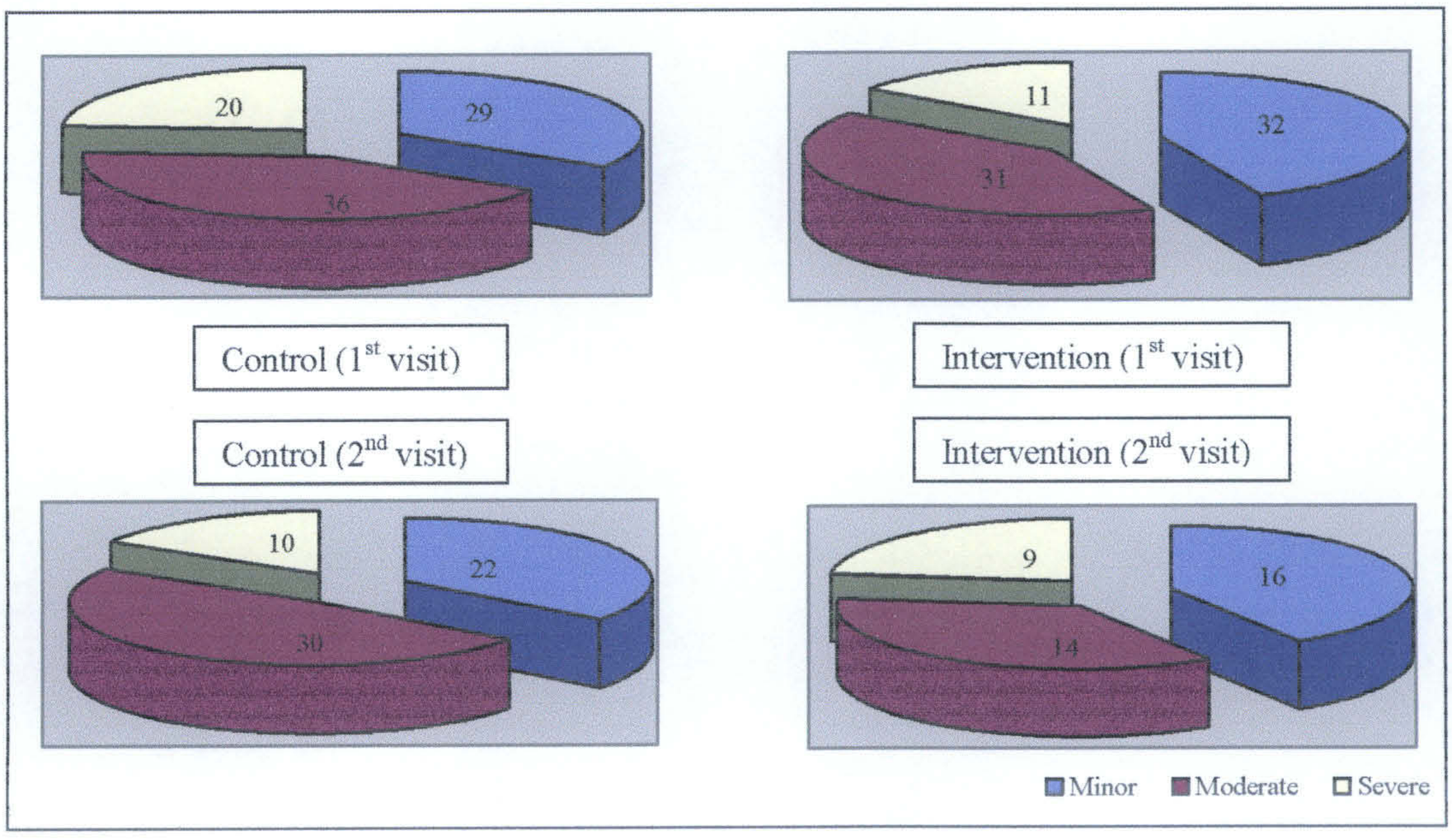
The decrease in the numbers of the intervention domains for the patients in the intervention group between the first assessment and the second assessment was statistically significant at both prescriber and patient level (Wilcoxon Signed-rank test, P=0.005 and 0.000 respectively). This decrease agrees with the decrease in the number of problems needing interventions from the first to the second assessment.

5.7.2 MRPs Classification Using Medicine or Service-Relate Effects.

Because the PCNE system does not quantify the severity of the identified problems and because of its inability to consider the service-related problems, medication-related problems were further classified using a novel system. This system categorizes the MRPs according to its severity into minor, moderate and severe and according to it sources into two categories, medicine-related and service-related classes (Section 2.3.7.2). Patients in both intervention

and control groups were compared for the rate of the MRPs and the effect of the medication review on this rate.

Figure 5.7 Different categories of the identified MRPs[*]



[*]Numbers on each sector represents the numbers of identified MRPs in each category

Medicine-related problems were classified into three categories according to the degree of the severity to minor *e.g.*, Constipation caused by DHC, patient was not taking the correct dose of Lactulose, repeating old Frumil rather than newly prescribed Frusemide, moderate *e.g.*, vomiting caused by Tramadol, uncontrolled pain while on Paracetamol, interaction between cardiovascular medication and severe *e.g.*, potential overdosing, bleeding while on Warfarin, blood pressure was not controlled with the prescribed medication after leaving the hospital and dependency cause by Rohypnol).

When the patients of the two groups were compared for the numbers of the MRPs identified in each group, it was found that the total number of problems was higher in the patients of the control group compared to the intervention group during both domiciliary visits. When the mean numbers of problems was calculated, it was found that the mean numbers of the MRPs in the control group (1.73 problems/patient) was higher than that in the intervention

patients (1.48problems/patient) during the first home visit .A statistical difference was observed between the mean numbers of the problems in each group during the second home visit (Mann Whitney U-test, P= 0.02). It was difficult to carry further statistical analysis on each category due to the small number in each cell, but when the total number of problems were compared during both home visits, there were significant differences between the two groups (Chi-squared test, P= 0.05 and P=0.01 respectively).

The mean numbers of the problems decreased to almost two thirds for the patients in the intervention group (0.98 problems/patient) between the first and the second home visit. When each group of patients was compared for the changes in the MRPs from the first to the second assessment, it was found that there was a significant decline in the number of the moderate problems for the patients in the intervention group (Wilcoxon Signed-rank test, P=0.004). The number of problems in the other two categories declined as well. The analysis as expressed as numbers of patients experiencing one or more problems is shown in Appendix XXIII.

Table 5.19 Different categories of the identified service-related problems

Category	Number of Problems (%)*			
	1st Visit		2nd Visit	
	Control	Intervention	Control	Intervention
Polypharmacy	0	6 (8.5)	2 (2.5)	1 (2.8)
Interface Issues	17 (19.8)	6 (8.5)	6 (7.4)	4 (11.1)
Patient Knowledge	27 (31.4)	29 (40.8)	27 (33.3)	9 (25)
Physical Difficulty	8 (9.3)	7 (9.9)	7 (8.6)	3 (8.3)
Label Problems	3 (3.5)	3 (4.2)	6 (7.4)	2 (5.6)
Compliance and Memory	25 (29.1)	17 (23.9)	26 (32.1)	16 (44.4)
Storage Problems	6 (7.0)	3 (4.2)	7 (8.6)	1 (2.8)
Total Number of Problems	**86**	**71**	**81**	**36**
No. of Patient	**49**	**50**	**39**	**40**

*Column percent calculated by dividing the numbers of the problems identified in each problem category in each study group by the total numbers of problems of the same study group during each visit X 100%

The second class of this classification system is the service-relate problems. Interface issue problems represented problems caused due to poor or lack of communication between the

hospital and the primary care professions and lack of explanation for medication changes from hospital. This often results in reverting to pre-admission medicines or new medication prescribed during hospital stay not being prescribed by the GP *e.g.*, prescribing discontinued Frumil instead of the newly prescribed Frusemide and different brands of the same drug being used *e.g.*, using both Gliclazide and Diamicron. Physical difficulties included problems with opening child-proof containers, taking the tablets out of the blisters *e.g.*, using knife to remove Omeprazole capsule from the blisters, difficulties in swallowing tablets *e.g.*, Paracetamol tablets and difficulties in using inhalers. Label problems included wrong name, strength, dose or frequency on the printed label. Storage problems included improper storage conditions (keeping the medication under the sink) and using expired medication. Knowledge problems include patient's poor knowledge about their medication *e.g.*, stopping DHC because the patient thought she was prescribed it to control sickness not to control pain.

The mean numbers of problems for the patients in both the control and the intervention groups during the first home visit were 1.76 problems/patient and 1.42 problems/patient respectively and this difference was not significant (Mann Whitney U-test, P= 0.18). The mean number of problems for the control group (2.07 problems/patient) was almost two fold the equivalent value in the intervention groups (0.9 problem/patient) during the second visit with an obvious statistical difference between the two values (Mann Whitney U-test, P= 0.00).

There was no significant difference between the numbers of problems for the patients of the control group in both home visits (Wilcoxon Signed-rank test, P=0.38) but there was a significant decline in the number of these problems between the first and the second assessment for the intervention patients (Wilcoxon Signed-rank test, P=0.00).

For completeness, the numbers of patients with one or more service-related problems is shown in Appendix XXIV.

About twenty seven percent of the patients in the control group had identifiable interface issues at two weeks after discharge, but only 12% of the intervention group had such

problem. However, on the second visit 10-12% had such problems in either group. This may indicate that such problems are generally resolved post discharge but may be prevented by good communication. 46-49% of the patients in both groups had problems related to their lack of knowledge regarding medication. This percent decreased dramatically for the intervention group during the second home visit which reflects the effect of counselling and patient education the during the first home visit

5.7.3 Inter-Rater Agreement of Medication-Related Problem Categories

As the previously described classification is novel, inter-rater reliability test was used to validate this system.

Table 5.20 Degree of Agreement between the two raters expressed as mean Kappa score

Category	Mean Kappa Score			
	1st Visit		2nd Visit	
	Control	Intervention	Control	Intervention
Medicine-Related Problems (Mean score for both groups)	0.53 **(0.48 Moderate)**	0.44	0.44 **(0.57 Moderate)**	0.7
Service-Related Problems (Mean score for both groups)	0.79 **(0.79 Good)**	0.78	0.71 **(0.77 Good)**	0.84

Tables 5.20 represents the rating and the degree of agreement for the different medicine-related problem identified in both the control and the intervention groups during both the first and the second home visits. Each category was rated independently to identify the degree of agreement between the two investigators. It was worth calculating the degree of agreement for each group independently to ensure that the investigator was not biased while coding the identified problems as she was not a blinded rater. 0.53 was the average kappa value for the medicine-related problems indicating a *moderate* degree of agreement between the two raters. Regarding the service-related problems an average kappa value of 0.78 indicating a good degree of agreement between the two raters. Detailed Kappa scores are shown in Appendix XXV.

5.8 Hospital Readmission

Patients of both intervention and control groups (122 patients) were compared for the effect of the hospital discharge planning and medication review on their rate of the hospital readmission in a period of six months from the first date of the discharge.

Table 5.21 Rate of hospital readmission in a period of six months

Number of Readmissions	**Number of Patients (%)**	
	Control	**Intervention**
None	35 (57.4)	34 (55.7)
Once	12 (19.7)	14 (23)
Twice	8 (13.1)	6 (9.8)
Three times	3 (4.9)	2 (3.3)
>3 Times	3 (4.9)	5 (8.2)
Total No. of Patients Readmitted	**26 (42.6)**	**27 (44.3)**
Total No. of Patients Readmitted due to MRPs	**6 (9.8)**	**3 (4.9)**
Total No. of Females Readmitted	**16 (26.2)**	**18 (29.5)**
Total No. of Recruited Patients	**61**	**61**

Table 5.21 represents the number of the patients readmitted to the hospital in a period of six month from the date of hospital discharge. The percent was calculated by dividing the number of patients admitted by the total number of recruited patients in each group. When the patients of the two groups were compared for any difference in the rate of their hospital readmissions, it was found that there was no significant difference in this rate (Chi-Squared test, DF=1, $P<0.05$).

Two third of the readmitted patients in both the control and the intervention groups were women. Nine (7.4%) patients were readmitted because of medication-related problems. Because of this small number, it was difficult to do any correlation analysis between this number and other factors *e.g.*, number of medication, type of medication, gender, patient's knowledge or patient's compliance.

Summary

- No statistically significant differences were found between the characteristics of the two groups and they were similar in the rate of dropout and other baseline data.

- No statistically significant differences were identified between patients of both the control and the intervention groups with respect to their knowledge about their medication at baseline.

- No statistically significant differences were observed between patients of both the control and the intervention groups with respect to most of the criteria of the NHP at baseline.

- Patient education on discharge resulted significant improvement in patients' knowledge and compliance scores as a result of counselling at discharge but further education on domiciliary visits resulted in little additional benefit.

- Enhanced discharge planning and patients education showed significant but small improvement of some areas of patients' quality of life at two weeks, but there was little difference at six weeks.

- Patients receiving structured education about their medications showed significantly higher level of satisfaction with the information they received.

- The total numbers of problems was higher in the control group compared to the intervention group during both home visits using both the PCNE classification system and the medicine and the service-related classification system.

- There was a decline in the number of the MRPs for the patients of the intervention group from the first to the second home visit and this number increased in the patients of the control group. The major contribution to this difference occurred due to improving patient knowledge and compliance.

- Identified MRPs were classified according to two classification systems; PCNE which is a validated system and the medicine and service-related system. The latter was validated for reproducibility.

- Medication review for the patients of the intervention group during the first home visit had a significant effect on reducing the number of the MRPs.

- The main causes for the MRPs were the manifested side-effects, poor understanding of instructions of use and/or administration of the medication and lack of communication between healthcare professionals.

- For the intervention group the prescriber was contacted concerning MRPs for about 34% of patients during the first home visit and about 10% for the second home visit.

- Medication review for the patients of the intervention group during the first home visit had a significant effect on reducing the number of the causes behind the MRPs, *i.e.*, interventions performed at the first visit had the most benefit and most of the interventions were at the service-related level (knowledge, compliance and interface) rather than the clinical level.

- The main interventions performed during the domiciliary visits were the patient medication counselling followed by informing the prescriber about the MRPs.

- The intervention group demonstrated a significant reduction in the moderate MRPs rather than the minor and the severe problems from the first to the second assessment.

- Twelve patients of the control group suffered form interface issue problems during the first home visit while only half this number in the intervention group suffered from the same problem which reflects the importance of the liaison performed by the investigator with the GPs immediately post hospital discharge.

- Lack of knowledge and poor compliance were the main problems identified using medicine and service-related classification.

- Number of patients in the intervention group suffered from knowledge problems decreased from 23 during the first home visit to only 8 during the second visit while this number kept almost the same for the control group which indicates the positive effect of the patient education during the first home visit.

- Medication review for the patients of the intervention group during the first home visit had significant effect on reducing the mean number of the MRPs and the total number of patients suffering from these problems in the second home visit.

- There was from moderate to very good agreement between the raters of the medicine and service-related classification systems which indicates its feasibility to be used as a valid classification system.

- Hospital discharge planning had little effect on the rate of the hospital readmission rate.

CHAPTER SIX

DISCUSSION

CHAPTER SIX
DISCUSSION

In the introduction to this thesis, existing approaches used to improve the services provided at the interface between the primary and the secondary care were reviewed in the literature. A number of limitations were highlighted and it was concluded that there was a need to develop a practical methodology and tool with which to improve the service. This chapter discusses the results identified and presented in Chapter Five.

6.1 The Preliminary Fieldwork and Pilot Work

The preliminary fieldwork set out to identify and use existing systems available in order to improve the pharmaceutical care service provided to elderly patients on their discharge from the hospital. This research also set out to identify a practical and feasible methods and tools for identification of MRPs which could be utilized by any healthcare member to review patients' medication at home. At an early stage, the testing of the method and tool under the conditions proposed for this research study, clearly demonstrated that it could be used to assess different patients' outcomes.

6.2 The Main Study

6.2.1 Patients Characteristics

The demographic data and its characteristics were examined in Chapter Five in some detail mainly to ensure that the study subjects in both groups were well matched. The following discussion highlights any differences between the two groups, comparing the results with other similar studies in order to assess the generalisability of any findings.

6.2.1.1 Sample Size

Due to the twelve-month time-frame allocated for data collection in the main study, a manageable and workable sample of patients was recruited according to the time schedule. It was difficult to recruit all the patients from the Elderly Care Unit due to the nature of this unit, as patients admitted to this unit may be admitted because of factors other than clinical *e.g.,* social arrangements required, and their stay and subsequently their discharge depended

on resolving such problems. Because of this, the three General Wards were sought to recruit further patients. In all, 122 patients met the various inclusion criteria described in Chapter Three; sixty one patients were allocated to each group (Table 5.1). The sample size of the recruited study subjects in each group was similar to other comparable studies (Begley *et al.*, 1997 and Mannesse *et al.*, 2000).

Of the 18 studies that investigated interventions to improve discharge medication issues as described in section 1.5, only four contain larger numbers of patients. However, two of these (Nazareth *et al.*, 2001 and Duggan *et al.*, 1998) did not involve pre-discharge counselling and another (Begley *et al.*, 1997) concerned counselling by community pharmacists. The Raynor *et al.* (1993) study did involve counselling and greater numbers of patients, but the patients were randomised into four groups and also did not examine the affect of a follow-up counselling session. This is therefore one of the largest UK studies involving randomised controlled trials of pre-discharge medication counselling. One failing with hindsight was that no note was made regarding patients who refused to participate in this study or their reasons for refusal. This would have helped to identify any bias in recruitment. However, none of the intervention studies in this area reported rates of refusal or described any details of the process.

It was unlikely that any bias was introduced during the sampling process because there were no statistical differences between study subjects that completed the study and those who dropped out (further discussion in Section 6.6). The dropout rate in this study was quite high (35.25%) but this rate was similar to that reported by Sweeney *et al.* (1989) which also studied medication counselling and patients compliance. This dropout rate was higher than expected and than what was calculated in the pilot study (20%) which was used in calculating the study sample size. This may suggest that more patients should be recruited to overcome this difference between the expected dropout rate and the actual rate to make the sample size more representative for the whole population.

The reasons for dropout were the same for both groups and no significant differences were reported in the number of patients who completed the study (Table 5.2). Not all of the

intervention studies involving medication discharge reviewed in section1.5 described dropout rates. The 19% dropout rate in the first visit in the present study is mirrored in a number of other reports; Nazareth *et al.* (2001) at 20%, Smith *et al.* (1997) at 20%, Lowe *et al.* (1995) at 11%, Sweeney *et al.* (1989) at 15% and Anderson (1987) at 16%. Only Begley *et al.* (1997) had a very much lower rate at 7%, whilst that from Horne *et al.* (1995) reported a dropout of 33%. There are comparatively few studies that have followed up patients for a period more than 14 days and amongst those that did so the present study had a similar dropout rates to the 35% by the second home visit, Sweeney *et al.* (1989) at 34% and Nazareth *et al.* (2001) 28%. The other follow-up study by Begley *et al.* (1997) has a very low rate at only 8%. The reasons reported for dropout in other studies are very similar to those described in the present study, with death very high in the list of reasons, as would be expected in this patient population. Overall the dropout rate is within the same range as other similar studies and no particular bias in the patient population should exist, validating the comparison with other studies.

Four percent of the total number of the present study subjects refused to complete the study after signing their consent forms which was somewhat lower than those reported by Walker and Pennington (1989) at 24%, although the latter study focused mainly on compliance among the elderly in the community rather than the recently discharged patients. The main reason given by the patients in the present study for their refusal to complete the study was the lengthy pattern of the questionnaires (2 patients). The other reason, was patient's refusal to have strangers visiting them at their homes after leaving the hospital (2 patients) and one patient became confused and forgot they had entered the study.

6.2.1.2 Age

The age range (65-96 years) of the study subjects (Table 5.3) was almost the same as that investigated by Burns *et al.* (1992). In this non-controlled study 56 elderly patients (age range 65-98 years) were counselled prior to their hospital discharge by one of the pharmacists and then were visited at home five days post discharge for medication review. The home visits were performed by either another pharmacist, hospital doctor or hospital sister to report the new prescription issued or any changes happened to the patients

medication post hospital discharge. The involvement of more than one investigator in the home visit may cause the introduction of extra source of variation due to the experience variations of the different investigators which in turn would be another variable to be studied.

The mean age (78 years) in the present study was similar to average ages in other studies in the elderly to which this one could be compared. As discussed previously, the studies carried out in the 1970s did tend to show a slightly younger range of patients described as elderly, owing to the lower age profile at that time.

6.2.1.3 Gender

The majority (63%) of the study subjects in this project were females (Figure 5.1) and this is also found in other studies examining the area of pharmaceutical care and drug compliance which draw on a random population of elderly patients (Grymonpre *et al.,* 1998, Lowe *et al.,* 2000b, Thompson and Stewart, 2001b). In all these studies the ratio of male to female varied between 1:2 and 1:3. The same ration (1:3) was reported by Enato *et al.* (2003) although this study was carried on the general Nigerian population rather than elderly patients specifically. Other studies involving patient medication discharge counseling showed a similar ratio.

6.2.1.4 Mental Status Questionnaire Scores

Patients' cognitive function and mental status were assessed in this study using the Mental Status Questionnaire (MSQ). The MSQ was designed to be used as a screening tool and any score under 21 indicates some cognitive dysfunction. Patients' notes were reviewed to exclude those with any recognized cognitive problems or dementia. The main reason for excluding this category of patients was that their cognitive problems may affect their ability to respond to the questionnaires and they will be unlikely to respond to any intervention to directly improve compliance and knowledge. The other reason is that this group might be receiving more intensive home care and supervision and they will not get any benefit from the counselling sessions provided. Patients in the both control and intervention groups did not show any significant difference in their MSQ scores (Table 5.3).

6.2.1.5 Disease and Medication

Table 5.4 describes the pattern of diseases for which medications were prescribed. The table describes the total number of study subjects suffering from different diseases. Cardiovascular conditions were the main problems diagnosed in both groups. Similar results were shown in a study by Thomson and Stewart (2001a) where elderly patients were interviewed to explore their opinions about their receipt of prescription drug information from GPs and pharmacists and to determine the medicine information requirement of elderly patients. In this study, cardiovascular conditions were also the most commonly identified problems.

Comparison to other similar studies in terms of the range of medications prescribed is not easy as only two of the studies reviewed in section 1.5 gave appropriate details (Begley *et al.*, 1997 and Duggan *et al.*, 1998) and even they failed to report fully the range of medicines. They did describe a similar rate of cardiovascular prescribing at around 50% of patients. The two studies reported much higher rates for gastro-intestinal medicines (28-59%) and respiratory (45%). Both studies also examined prescribed medication in the patient's possession just after discharge and just over half of the medications in the study by Duggan *et al.* (1998) were laxatives which in many cases would have been prescribed by the GP. This may also have been true of inhalers used only occasionally and perhaps not prescribed in hospital. It is therefore difficult to compare the precise range of medication-related problems following discharge in these patients to other studies, but this aspect has not been well reported.

Around half of all the study subjects were diagnosed with hypertension. Infections were the second most likely conditions. More than 10% of the study subjects suffered from various arthritic conditions which may be a factor affecting patients' physical ability to administer their medication which in turn may affect patients' adherence.

It was common for the study subjects to suffer from more than one condition; the actual permutations of the combinations were too large for reasonable analysis to be done but the simple Chi-squared test did show that there was no significant difference between the two groups for the type and the number of conditions.

The study subjects had in their possession an average of seven (range 0-17) prescribed medicines on admission. The average number of medications prescribed by the hospital for patients to take home was eight (range 2-20). Therefore, the stated aim of achieving fewer medication on discharge compared to admission, particularly in the elderly, does not seem to have been achieved. The intervention in this study was to counsel patients after discharge medicines had been issued, rather than attempt a drug review and potentially contacting the prescriber before discharge medication had been arranged. Such a service may have some benefits in this group of patients, if only to review the number of medications being taken and would be a reasonable area for future research. Some schemes have described a service of pharmaceutical care from admission that did consider reducing medication on discharge. The study by Pickrell *et al.* (2001) which attempted such an approach found no reduction in number of medicines. Cantrill and Clark (1992) identified a slight increase in number of medications on discharge from 3.8 to 4.8.

In terms of numbers of medications prescribed at discharge compared to other studies, the value is in the upper range. Of the 11 studies involving discharge medication where numbers of medication are reported, two described a mean of 2-3, six reported 4-5 and three reported 6-8 medications. The two studies reporting the lowest range were conducted in the late 1970s-1980s. This may indicate the expansion of therapeutic options since that time.

The most frequently implicated classes of medications were cardiovascular medication (anti-coagulants and diuretics of different types), followed by nonsteroidal anti-inflammatory medicines (NSAIDs), then proton pump inhibitors (PPIs) and beta agonists and different types of laxatives. Patients were taking fewer OTC medicines than might have been expected. This is possibly due to the fact that the types of drugs normally purchased over-the-counter were likely to have been prescribed for these category of patients by their GPs (Appendix XIX).

There was no difference between the patients regarding the two groups in the number of used Dossett Boxes on admission. These boxes were normally filled by either the patients themselves, carers (family or health carer), or their community pharmacists. Patients were

using Dossett Boxes mainly because of dexterity or sight problems and inability to take the tablets out of the blisters. The other reason for using these boxes is confusion due to polypharmacy and patients being unable to take a number of medicines from the blister each time. The last reason to consider was patient's poor memory, and from a personal point of view, Dossett Boxes may not always help patients with memory problems. This is because of the observed tendency for such patients to forget to take any of their medication for a whole day, for instance, one of the stroke patients forgot to take her medication which included Warfarin from the box for several days, putting her at a very high risk of another stroke.

6.2.1.6 Types of Community Pharmacists

The majority (85%) of the patients were dealing with only one community pharmacy, and it was either the nearest to their accommodation, the closest to their GPs or the availability of a prescription collection services from. This percentage (85%) is similar to that reported by Cook (1995) who studied the transfer of information between hospital and community pharmacy. In Cook's study, patients who were recently admitted to the hospital were interviewed regarding their community pharmacy. Cook reported that 85.8% of the chronically unwell patients always use the same community pharmacy. One of the reasons for using more than one pharmacy in the present study was the inability of the patients to go to the pharmacy by themselves and depending on one of the relatives or carers to collect the repeat prescription from any pharmacy. A patient said she would go to Boots in case her local chemist would not have all her medication.

Most of the pharmacies involved in this study were independents (as type of business). Patients preferred to deal with such pharmacies rather than the multiples because of a more personal services provided. It was commented that they are normally more familiar with their customers than the multiple pharmacies, where the pharmacists in charge may change frequently.

Unfortunately, none of the studies involving community pharmacists involved in discharge schemes gave any indication of their demographics. For instance, it is possible that regions with a high proportion of independent community pharmacies may not be able to offer the

type of service compared to those where multiples formed a larger proportion. In terms of group matching it does appear that the intervention group involves a higher proportion of multiple pharmacies, but the difference is quite small compared to the overall proportion of independents. It may have been useful to collect details concerning the type of pharmacist running the pharmacy *e.g.*, age, experience etc. as well as their opinions on the advantages of the discharge information that they were sent. This is particularly in the light of the apparently low level of involvement of the community pharmacists in this study.

When the community-based pharmacists were contacted to inform them about the nature of the present study, it was clear that most of the independent pharmacies kept an accurate patient medication record (PMR) for each patient, which was not the case with the multiple pharmacies who may be keeping PMRs but not updated versions. The other problem that encountered with the multiple pharmacies in this study was dealing with locum pharmacists who were there for a short period of time and were not familiar with the regular patients so they were not that interested to offer help and if they showed interests, they could not offer too much help in the study because of the nature of their jobs. Although the majority of the community pharmacists contacted showed interest in the study and a desire to help, of the 58 pharmacists contacted, only four pharmacists (three independent and one multiple) filled the blank medicine information sheet sent to them with the TTOs and gave it back to the patients when they were collecting their repeat prescriptions.

It was not assessed in this study the extent to which the community pharmacists may have prevented certain interface issues. They may have been involved in resolving some of these problems in the intervention group and have played some part in reinforcing information to the patients. It would have been useful to ask the pharmacists to record any involvement with the discharge patients. Although this area has been investigated (Begley *et al.*, 1997 and Duggan *et al.*, 1998) more work is needed to quantify their real use of discharge information sent by the hospital.

6.2.1.7 Other Characteristics

Those patients supervised by carers may have fewer problems (Evans and Spellman, 1983), although other studies have not confirmed this observation (Wandless and Davie, 1977). In the present study, those patients not predominantly responsible for their medication were excluded. None of the study patients including the 13 patients, who admitted receiving help from family or carers (Figure 5.2), were totally reliant for day to day assistance. Some received an occasional reminder to take medicine or to have the prescription refilled or the dossette box prepared. Similarly, for those who received help from a district nurse, only those who received visits less that once a week were included in the study. It is worth mentioning that most of the patients were living alone, and there was no difference between the two groups in this respect.

This general approach is that taken by nearly all of the other studies concerning discharge medication. It would be interesting to construct a study that examined counselling given to the patients' carers. In that way it may be possible to examine the schemes that also included the elderly with poor cognitive function, a group very rarely studied in this context.

In general, the patients recruited to this study do have the characteristics of those in other published studies concerning discharge medication in the elderly. It is therefore justifiable to draw comparisons to such studies

One of the major drawbacks to generalizing the findings is that the study was conducted in a single London teaching hospital and patients were visited in the main in just one Health Authority – Lambeth, Southwark and Lewisham (LSLHA). However, patients in the present study were recruited from various geographical locations within this health authority to ensure diversity.

With one exception, all the UK studies that examined discharge medication were also only conducted through a single site. The patients' characteristics and many of the findings were not dissimilar to that found in other studies and it can be argued that the present study is

generalizable to other settings in the UK, There is an obvious need for multi-centre studies but this is true of much pharmacy practice research.

6.3 Conduction of the intervention and assessment

The process of discussing and reviewing medicines with patients is often termed "counselling". Sparing enough time for patients to be counselled by one of the pharmacists prior to hospital discharge was a standard discharge requirement in St.Thomas' hospital. Practically speaking, pharmacists failed to fulfill this requirement and most of the study subjects in the control group admitted receiving no in-depth counselling by the ward pharmacist. This may be attributed to various reasons. Firstly, there was a shortage of pharmacy staff covering the four elderly wards unit, as there was only one permanent C-grade pharmacist and one basic grade pharmacist who is normally rotating in different areas for period not longer than nine weeks. Another reason might be the rushed unplanned discharge, which does not give pharmacy staff enough time to carry out the counselling sessions. A further reason to consider is the pharmacists' beliefs that the patients were on these medications for a long time and they did not need any sort of education.

Asking patients of the control group about the counselling they received and who provided such counselling was the only way to gather the information as it was very difficult to keep shadowing the ward pharmacist while they were preparing for the discharge. Shadowing the pharmacists or asking them directly about their counselling activity may cause some bias and at the same time may affect the pharmacist's normal counselling rate by making them carrying out more counselling sessions. For the intervention group, each in-patient counselling procedure took an average time of about 23 minutes. Thus, to counsel the 61 patients, it would have involved approximately 24 hours of staff time. It is worth mentioning that many patient were observed to be anxious to leave the hospital and they were unsettled and sometimes unresponsive to the information provided at the time of discharge, therefore providing written information was an effective means of supporting the verbal information.

Of the intervention studies in the literature very few either describe the structure of the session in any detail or noted accurate timings of the session. The counselling sessions

themselves seem to be very much of a similar pattern to that used in this study (Appendix II and XIII). The counselling strategy by Cantrill and Clark (1992) covered almost the same format and was reported as being delivered in a median of 10 minutes (range 5-40minutes). Sweeny *et al.* (1989) did not employ a checklist, the process seeming to be left up to the pharmacist to decide on 'explaining the regimen in detail' and no time taken is described. Edwards and Pathy (1984) simply stated that they used a 'standardized counselling procedure'. Similarly, Johnston *et al.* (1986) mentioned a '15 minute tablet instruction session'. Begley *et al.* (1997) on the other hand described details of the areas covered and appeared to include the same material as the present study. A qualitative study by Ryan and Chambers (2000) utilized an educational model for conveying information to patients concerning their medication. This is based on Knowles principles of adult learning (Knowles, 1990) where attempts were made to motivate the learners' readiness to learn *i.e.*, discussing why it is important that people are aware of certain information regarding their medication. The approach was adopted where possible in the present study. No other studies involving discharge medication counselling have attempted to describe a model of education.

Therefore, the approach to medication counselling does appear similar to other discharge counselling studies where this has been described, although of a slightly longer duration. It is difficult to tell if the extra time would have a great impact of outcome. Most studies also included written patient information cards of some form. It could be argued that what is being achieved during such sessions is not counselling but simply patient education. A strict concordance approach was not adopted, which is closer to a traditional counselling model as it addresses the patients own issues regarding medication. This was because such an approach would have entailed tailoring the patients' regimen at the point of discharge, which would be impractical and outside the remit of this study. The researcher did not attempt to explore the patient's feelings towards medication as it would affect compliance.

It is apparent from the literature that the process of 'Discharge Medication Counselling' has not been well studied or formalized and does not appear to be grounded in any theoretical framework. Further useful educational research could be undertaken in this area.

6.4 Domiciliary Visits

The need for home services was recognized in the Department of Health and Pharmaceutical Profession joint working party (DoH, 1992), which stated that "*arrangements should be introduced to provide domiciliary pharmaceutical services for patients who are unable to use the pharmacy in persons*". In this section the effect of the structured discharge counselling performed prior to hospital discharge and during the home visits is discussed and compared with other similar studies.

6.4.1 Time and Duration of Home Visits

Out of the 122 recruited study subjects, 99 patients received one domiciliary visit and 79 patients managed to complete both the first and second visits. The first home visit was planned two weeks after patient discharge from the hospital as every patient received medication sufficient for only two weeks. The second home visit was performed four weeks (six weeks after the discharge date) after the initial visit as many of the patients would obtain a repeat prescription on a monthly basis.

The total time spent (Table 5.8) to complete all the domiciliary visits (first and second) was about 118 hours (about 45 minutes per patient for the first visit and 33 minutes per patient for the second follow-up). The first domiciliary visit for the control group took about 39 hours (average of 45 minutes per patient) and 22 hours (average of half an hour per patient) for the second domiciliary visits. All these times did not include the travel time. Before starting the main study, the planned time period to be spent with every patient was expected not to exceed 30 minutes, but practically speaking, this was difficult to achieve especially during the first assessment. The investigator tried to familiarize herself with the patient's environment and at the same time many of the patients were living alone and were very happy to have someone to visit and to speak with about their medical or even social problems.

There was no significant difference between the total times spent with the study subjects in both groups. The long period the investigator spent with the control group may be attributed to the fact that the investigator was trying to discover the medication-related problems they

suffered. It was anticipated that there could be ethical issues concerned with not acting upon medication-related problems of the control group patients. To overcome this issue the investigator reported any serious problems in the control group to the senior clinical pharmacist in the Elderly Care Unit in St. Thomas' Hospital. In practice, very few MRPs of a serious clinical nature, other than poor medication knowledge were noted in either group and most of these serious problems were potential rather than actual so that the senior clinical pharmacist did not feel that immediate action needed to be taken. During the second home visit, the investigator informed the patients of the control group regarding the most serious problems and the action needed *e.g.,* contact the GP.

The second home visit was of shorter duration for both groups, as less time was needed by the investigator to be introduced to the patients, and no time was needed to give patients any education (for the intervention group only) at the second home visit, which was mainly designed for assessment rather than for further education. In a similar study by Al-Rashid *et al.* (2002) where patients recently discharged from hospital were followed-up in their own home and an estimate made of the time spent, being one of the few studies where patients were counselled both before and after discharge. The pharmacist gave domiciliary visits to 43 intervention patients and 40 control patients and those visits took approximately 24 hours and 40 hours respectively excluding travelling time. In Al-Rashid's study, more time was spent with the control group patients *i.e.,* one hour per patient because they were given more time to correct the mistakes regarding administering their medication, as the researchers considered it to be unethical not to correct wrong or missing information. This extra time was needed as patients in this group had not been counselled pre-discharge.

Time spent during the domiciliary visit is critical for economic viability and 30-35 minutes seems to be the norm for this type of service offered to the elderly. However, the full cost should include an estimate of travel time which does not appear to have been estimated in any other studies, and perhaps should have been done so in the present study. It would however, have been difficult to generalize the findings as the researcher used public transport in London, a situation unlikely if actually delivering a domiciliary service.

6.4.2 Patients Compliance

One of the aims of this study was to ensure that some changes to compliance was brought about through the discharge procedure and domiciliary visits rather than measuring the absolute compliance values. Patients' adherence to the medication regimen was assessed in this study using tablet counts and it was calculated as the mean percent score of the total number of medicines administered to every patient.

6.4.2.1 Results from present study

Compliance is one of the most widely used measures to assess the effectiveness of medication counselling and is also used as an outcome measure in other studies involving medication discharge counselling. Table 5.11 describes the results obtained from tablet counts during the first and the second home visits. Compliance was quantified as the percentage of the correct amount of medication being administered by the recruited patients. The other expression used in this study to quantify compliance was the percentage of the compliant or non-compliant patients. There has been much debate concerning the most acceptable level of good compliance.

In the present study, the study subjects were categorized according to their behaviour towards their medications into three categories; compliant, overuse and underuse classes. A range of 85-115% compliance level is adopted as an acceptable range to describe good compliers. Study subjects were asked to show all the medications they had at home for the purpose of reviewing these medications and they were not informed that their tablets would be counted to measure their adherence. Despite the lack of consistent baseline data in the present study during the first home visit, the counselled group did appear to do slightly better than controls on the initial assessment. The assessment of compliance during the second home visit should be accurate as baseline home-stocks were available (from the first home visit) and detailed prescribing and dispensing data was available.

From table 5.11, it can be observed that, the mean compliance scores are very high in both groups at the various stages of assessment. This has been the finding in a number of other studies described in section 1.5 and will be further discussed below. The assumption is that

patients recently discharged from hospital will have a higher adherence level which declines over time as perhaps motivation is reduced. This is not a universal finding and has not been properly investigated. The translation of improvement in compliance to clinical benefit is also difficult. There are some drug groups and conditions where a tight compliance band is important and others where it is of less relevance.

Table 5.11 does indicate that a 10% better level of compliance compared to control is achieved through pre-discharge counselling. After further counselling on the first home visit the compliance level by this measure had increased by only a further 5% in the intervention group and remained unchanged in controls. In view of the already high compliance level there would seem to be little advantage in counselling during a follow-up visit at two weeks.

It has been described in section 1.4 that there is a consensus that good compliance is within the range of 85-115% *i.e.*, outside of this range could have a detrimental effect. If the data is analysed as in table 5.12 there is a dramatic effect such that only 55% of control group patients are compliant compared to over 70% of the intervention group by this definition. The data does seem to support a decline, though non-significant, in the control group over time. It also supports the observation that further counselling for the intervention group during the home visit provides little added benefit. The figures should also be taken in context in that although outside the range of 85-115%, many of these patients were just a few percent below or above the cut off point, making the true clinical significance difficult to quantify.

No association was found between the number of medications study subjects were prescribed on discharge and patients' adherence to their medication during the first home visit. This finding supports those found by Blenkiron (1996) where 80 patients aged 75 years and over were interviewed to assess their compliance level. However, this study focused mainly on patients' compliance in the community. This finding does not support the hypothesis that the multiple pathology of aging encourages polypharmacy which in turn is associated with poor compliance (Burns *et al.*, 1992). Age also showed no link with patient's adherence to the

medication regimen and this supports the phrase "*Non-compliance is a problem for all ages, with each group having their own particular problems*" (Raynor, 1992).

6.4.2.2 Comparison to other medication discharge studies

When comparing these findings to other studies that involved discharge medication counselling, a fairly consistent picture is seen of generally high levels of compliance, improved still further by the intervention. Not many have examined the effect of a second follow-up visit in which counselling also takes place, as in the present study. The identified UK studies are discussed below and should be taken in the context of their many shortcomings as described in section 5.1.

Of the non-intervention studies Parkin *et al.* (1976) reported that, 75% of patients were within the 85%-115% compliance level two weeks after hospital discharge, but they did not include those who did not understand their regimen, explaining the somewhat higher value than the present study. Similarly, Eagleton *et al.* (1993) reported 78% of patients compliant by this definition. This can also be explained as Eagleton *et al.* (1993) included younger patients (age range of 5-75 years) in their study.

As mentioned previously, Al-Rashid *et al.* (2002) was one of the few studies to include further counselling on a post discharge visit. They chose to express compliance somewhat differently as a percent of all items prescribed where compliance fell between 85-115%. The problems of using such a method are described in section 1.4, and it is not as useful as presenting the data as a mean with standard deviation/confidence intervals or percent of individuals reaching a certain mean range with the entire regimen. Using their system, Al-Rashid *et al.* (2002) observed a 30% improvement as a result of further counselling and concluded that a follow-up visit was worthwhile. Their compliance rate for controls at second visit was just 16% compared to 70% in the intervention group. The first visit only measured a 50% compliance rate in the intervention group, which is very much lower than any other study.

The study by Nazareth *et al.* (2001) did not include discharge counselling as part of the intervention, and although patients were visited at home by community pharmacists there was no counselling procedure described although they were instructed to correct adherence problems. A decline in mean compliance rate was seen being 75% 1-2 weeks after discharge, 52% at 3 months and 45% at 6 months. This is a similar picture to the control group in the present study and supports the observation of declining compliance following discharge.

Smith *et al.* (1997) only described competence in terms of the pharmacist 'feeling there was a problem'. This crude estimate resulted in 85% of patients being rated as compliant in the control group and 95% in the intervention group and the 10% difference again reflected in the present study. Binyon (1994) only assessed 15% of patients in their prospective single cohort study and 73% appeared to have 100% compliance as a result of discharge counselling, indicating reasonable levels of compliance. Lowe *et al.* (1995) calculated a mean compliance score in a similar way to the present study showing 95% compliance 10 days post hospital discharge for the intervention group and 83% for controls again consistent to the findings described in this study.

Although Begley *et al.* (1997) study involved post discharge counselling using community pharmacists their finding were consistent with the present and other studies. Compliance was 94% at two weeks after the counselling session compared to 76% for controls while the study subjects in the present study showed a compliance score of 85% for the intervention subject in comparison with 75% for the control group during the first home visit. The community pharmacists subsequent visits seemed to show no further effect on compliance as might be expected at this very high level. The same findings were identified in the study by Raynor *et al.* (1993) which involved pre-discharge counselling and a great emphasis on information sheets. Again mean compliance rates were approximately 10% better in the intervention group; 95% compared to control at 86%. One of the reasons explaining the difference in the compliance level between the Raynor *et al.* (1993) study and the present study may be due to the difference in age range; while the present study focused on elderly patients, Raynor's study recruited a younger population. Also, the study was blinded and tablet counts made without the knowledge of the patients. The similar findings to the present non-blinded study

go some way to validating the results. Also, if blinding was significant then a generally higher compliance level would be expected in the present study. Another explanation for the difference in compliance levels between this study and the Raynor's study may be the inaccurate assessment of the compliance during the first home visit, due to the possibility of using or mixing old and new medications. Other reasons may be the absence of the original packs or the original labels with the actual dispensed amounts or keeping more than one stock in different locations. This inaccuracy was avoided in the Raynor's study by taking all the old medications patients had away and reducing the possibilities of their obtaining a further supply from their GPs by providing them with fresh supply. Although there is difference between the two studies in the compliance percent, both percent considered to be high. An important factor in these relatively high levels of compliance is that the patients were recently discharged from the hospital and may be more motivated to adhere to their regimens. The study by Edwards and Pathy (1984) also conformed to the usual findings at 75% for controls and 90% for intervention groups at one week.

Sweeney *et al.* (1989) also observed somewhat higher levels of compliance than in the present study, measuring this as percentage of patients falling in the 85-115% range. The observed 75% of patients compliant at one week post discharge in the control group compared with 95% in the intervention group. This 20% difference using patient numbers is similar to the 20% difference in the present study though at a lower rate. They observed no decline in numbers compliant at six weeks, unlike other studies.

Horne *et al.* (1995) reported slightly lower general mean compliance levels at 2 weeks post discharge; 67% for controls and 76% for the intervention group, but again a 10% difference. Also, consistent with the present study both groups showed a 10% fall at two months, no counselling being given at the first home visit.

6.4.2.3 Conclusions

In fact, for the stated aims of the present research *i.e.*, to determine the effects of counselling, an accurate tablet count to show individual changes in compliance was not required. As both groups were randomly allocated and tablets counted in the same way, any errors in

assessment of compliance would have been distributed randomly over the whole study population. Accordingly, it was more important to determine whether or not the counselled group showed any improvement in their adherence level. There was still a small but significant improvement in compliance level for the counselled patients six weeks after leaving the hospital. This may be attributed to the supported education sessions provided to this group two weeks after hospital discharge which emphasized the importance of adherence to the medication regimen. While intervention patients showed an improvement in their compliance levels, control group patients showed a decline in their adherence level with time and this decline in compliance rate over time was also reported in a previous review (Eraker *et al.,* 1984).

Despite the limitations to tablet counts described in section 1.4, the findings regarding discharge counselling is very consistent with an improvement of 10-20% at 1-2 weeks post discharge. The higher figure is often achieved if compliance is rated by the number of patients falling in the range 85-115%. This is despite some studies not being blinded, non-randomised and sometimes poorly controlled. Thus, despite the potential sources of bias in the present study, consistent results have been found.

One other limitation of the present study was that only one method of assessment of compliance was employed. It would have been more useful also to assess compliance in another way such as by questionnaire to further validate the findings. This would however have placed an increased burden on the interview time with patients, which was already very high. In addition, arrangements to count tablets away from the patients and provide new supplies could have reduced bias, but was logistically difficult to arrange.

In addition to the previously mentioned inaccuracies, tablet counting measures only the amount of a drug taken, not whether it was taken at the right time or not. The investigator therefore, asked the patients how many times a day they took their medicines, how many doses and the actual time they took the medicines. Also the tablet counts were performed unblinded by the same investigator (NMS) who delivered the counselling sessions. Although

this is a main source of bias, it was impossible to get help from another worker to perform the tablet counts and home visits for time and funding reasons.

Of course the clinical significance of these changes could be debated and will depend on the clinical situation. The generally lower levels of compliance in the present study compared to some others are difficult to explain, but may be related to the higher numbers of drugs prescribed (Section 6.2.1.5). The conclusion is that pre-discharge counselling does improve compliance, perhaps maintained by a subsequent home visit, but in terms of a service from a dedicated liaison pharmacist such home visits are probably not worthwhile.

There are further studies that need to be undertaken regarding the most appropriate intervention to maintain adherence post discharge. It may well be more appropriate for a primary care worker to visit patients some months after discharge to identify those with the poorest compliance levels. As mentioned previously, little is known regarding motivations to take medication post discharge and the factors contributing to a decline in adherence.

6.4.3 Patients Knowledge

6.4.3.1 Results from the Present Study

Patients knowledge was assessed by interviewing the patient at his/her bedside using the structured questionnaire described in Appendix IV. This was calculated as the mean of the scores for medication knowledge for each of the eight questions asked divided by the total number of medicines prescribed for each patient. The mean score for all the patients in each study group was calculated for final comparison between the two groups. The assessment of participants' knowledge at the beginning of the study and before starting any education programme proved to be a useful method of obtaining key information and base-line medication knowledge.

It is apparent from Figure 5.3 that the study subjects of both groups were well matched in their knowledge level before counselling. Results indicate that patients' awareness of medication strength and side effects was very poor. These results together with those described in previous studies (Williamson *et al.*, 1992, Eagleton *et al.*, 1993 and Thompson

and Stewart, 2001a) have shown information about medication-related side effects to be a priority for elderly patients. Patients knowledge regarding the medication name, use, shape and dose was quite high (more than 50%) for study subjects in both groups during their hospital stay. The main conclusion for these results is the importance of tailoring education programmes to meet the needs of the older people including the name, purpose, some of the most common side effects, storage and dosage of the drugs.

The number of medicines patients were taking during their hospital stay did not significantly influence (Figure 5.4) the patients knowledge score, *i.e.,* no correlation between the composite score of patient knowledge and the total number of medications for each patient, but it was observed that those taking 15 medicines showed the lowest level of knowledge and patients on two-medicine regimens showed the highest knowledge level.

At the time of this study, St.Thomas' Hospital approach to providing drug-related information to patients for discharge was unstructured and with no standard counselling protocol. In addition to the fact that in a busy hospital like St.Thomas' with high patient turnover, patients may be inadequately prepared for the discharge and handed their medicines immediately prior to discharge, most of the time by the ward nurse. This situation was found in other hospitals in the UK *e.g.,* Kent and Canterbury Hospital (Oborne and Dodds, 1993). For these reasons, structured counselling sessions were planned for each study patient according to his/her needs and enough time was provided for questions and concerns.

This study was designed to assess discharged patients' behaviours towards the medication-related information they received prior to their hospital discharge. The total knowledge score was calculated for the total number of patients in each group by summation of the eight questions and calculating the mean percent. The patients in the two groups were well matched at the baseline level (Figure 5.4) during their hospital stay; there was no significant difference between their scores. When the total score for the patients in the two groups (Table 5.9) was re-assessed after hospital discharge, it was found that patients' recall of the drug regimen was significantly better in the counselled patients in comparison with the

control patients, *i.e.*, the total score was higher for the intervention group during both the first and the second assessments.

Patients of the intervention group showed an improvement in the total score during both first and second assessments, but this improvement only reached level of significance during the first assessment. These results suggest the importance of providing counselling sessions prior to hospital discharge rather than during the domiciliary visits. Patients of the control group showed a significant decline in the total score in the second assessment.

When the study subjects were compared for each drug information criterion individually, it was observed that in both groups, knowledge concerning the medicine name, purpose and shape was high as might be expected in patients who had been taking the same medication for a long time. Patients in the intervention groups showed a higher knowledge level with regard to all the knowledge criteria except the knowledge about the drug strength on the first assessment in comparison with the control group patients (Table 5.9). When the two groups were compared for any difference during the second home visit, significant improvement was shown for intervention patients' knowledge about their medicine strength, dose, frequency, special instruction and side effects.

When the patients were monitored for any changes in the level of their knowledge after leaving the hospital, it was observed that intervention patients showed improvement in all the knowledge aspects which reached a level of significance two weeks after their hospital discharge. Patients awareness of medications' side effects and special instructions was very poor before leaving the hospital *i.e.*, study subjects of both groups showed a very low knowledge score regarding side effects and the special instructions prior to the hospital discharge. When these two aspects were reassessed during the first home visit, patients in the intervention group showed 100% increments in these two aspects. The improvement in these scores is probably due to the fact that the investigator focused to a greater extent on these two criteria during the counselling sessions.

This improvement in intervention patients' knowledge scores after hospital discharge indicates the importance of providing patients with structured education sessions prior to hospital discharge and tailoring these sessions according to their needs.

When changes in patient's knowledge were calculated while moving from the first home visit to the second home visit, an improvement in intervention patients' knowledge about medicine shape, dose, time of administration and the special instructions was reported. However, these improvements did not reach any level of significance. Patients in the control group showed a decline in their knowledge about medicine strength, dose, time, special instructions and side effects during the second assessment. This decline was not statistically significant except for drug strength and drug frequency. It might be inferred from this data that counselling to improve medication knowledge prior to hospital discharge has some benefit, but further counselling after discharge may have a lesser impact.

No clear association was observed between the number of medicines patients were prescribed on discharge and knowledge scores. Also, no linear relationship was demonstrated between the adherence pattern and knowledge level. It is interesting to note that patients counselled in this study showed increased knowledge and compliance levels, but no relation was proved to exist between them. Studies on counselling patients about their medication have shown variable effects on both patients adherence and knowledge. Some studies reported an increase in both patients knowledge about medication and compliance level (McDonald *et al.*, 1977 and Edwards and Pathy, 1984). Another study reported that the poor patient knowledge about their medication did not adversely affect their compliance level (Eagleton *et al.*, 1993). Similarly, patients in the Michalsen *et al.* study (1998) showed the highest level of understanding for Coumarin and Frusemide; however, their knowledge level was not significantly correlated with their compliance with drug treatment.

Because it is believed that elderly patients suffer from memory problems, it was quite useful to provide them with the written information to support the verbal session. Although written information cannot take the place of discussions between patients and pharmacists, providing patients with written information reinforces these discussions. This may be another reason

that the counselled patients in this study showed a higher level of knowledge in comparison with the control group patients.

6.4.3.2 Comparison to other studies involving discharge medication

As stated previously, it is very difficult to compare studies that report the effect on medication knowledge as a result of discharge counselling. This is because of the very different scoring and assessment processes employed by the various researchers. Within this limitation a comparison to other studies is described below.

Al-Rashid *et al.* (2002) noted a high knowledge score (above 85% in their system), for the knowledge of medication regarding 'dose interval' and 'dose taken' at the first visit post hospital discharge. They did not assess knowledge at baseline in these two areas and the counselled group scored about 10% higher. This equates to the findings in the present study regarding the dose and frequency scores. Also, as in the present study no changes in such scores were seen between the first and second home visits. The meaning of their term 'drug use' is not defined but probably relates to special instructions. If this is the case then the overall difference of about 30% between groups that they observed is in line with the present findings, although their overall scores in this category is very much higher. As this is the only study examining directly the influence of a post discharge counselling session, it would seem to support the conclusion that knowledge is not improved as a result of the first home visit. The study did not assess categories such as adverse effects, purpose of medication etc.

The study by Lowe *et al.* (1995) focused on knowing the purpose of medication as a marker of drug knowledge, although the intervention in this case was a self-administration scheme whilst in hospital. This reached the same level as the present study on the 10 day visit at 90% correct, but the control group scored just 40% and it is unclear from the paper how the percent score was calculated. Although Begley *et al.* (1997) also offered no detailed description of the scoring system used, the control group patients showed a mean of 73% at the baseline. It is of interest to note that two weeks after the counselling session there was a mean difference of 10% between control and counselled groups, but at one month this had

not changed despite further counselling. Without knowing the scoring system it is difficult to comment on the higher mean level, but the findings are broadly in line with the present study.

Raynor *et al.* (1993) assessed knowledge by describing numbers of patients correctly answering three questions regarding their regimen; frequencies, dose and correct timing. In the present study, timing was not explicitly asked but considered as the frequency of administering medication *e.g.* three times a day, twice a day etc. The composite score seemed to show quite a low value of 47% for controls compared to a similar calculation in the present study. This improved by over 20% in the intervention group in the Raynor's study. This is possibly the result of a more sophisticated individualized information card provided.

One of the few studies to report no improvement in knowledge was that by Horne *et al.* (1993), but no details are provided in their brief abstract. Edwards and Pathy (1984) reported better knowledge of regimen after counselling patients recently discharged, but again no details were provided on the way that this was assessed. This problem of identifying knowledge scores was well illustrated by the abstract from Davidson and Hall (1989) where knowledge was just one element of a total 'ability score' to manage medicines. They did find significant improvements in the score as a result of discharge counselling and reported the biggest improvement in knowledge of side effects and knowing the purpose of medication. Again, no figures were presented so comparisons are difficult. Even more difficult to compare is the study by Anderson (1987) who made a subjective assessment of knowledge as being 'sufficient', finding that pre-discharge counselling improved the numbers in this category.

Eagleton *et al.* (1993) provided a useful baseline with which to compare the results in the present study. They observed that after discharge more than 85% of patients knew the dose, frequency and route of administration only about 10% higher than in the present study. They also noted a low level of knowledge of side effects, as only 30% could name a single side effect a finding which was reflected in the present study.

6.4.3.3 Conclusion regarding knowledge assessment

From the limited data available, it does appear that other studies support the findings of the present study; knowledge improves as a result of pre-discharge counselling. This is one of the few studies that fully examined the influence of further counselling in the patient's own home and this seems to have little additional benefit. Future studies will be needed to validate a standardized method of evaluating knowledge and clearly define the areas of knowledge most difficult to improve or of greatest importance. For instance, although side effects appear to be the area of poorest knowledge, the importance of patient awareness of potential side effects has not been well evaluated.

The main limitations of the knowledge assessment involve the non-blinding of the interviewer, which applies to most of the assessments in this study. However, the consistency of the results compared to other studies would indicate that this may not be a source of bias. The system used to assess knowledge was not fully validated, but this is also true of most similar studies. It is also the case that patient knowledge was tested without patients looking at labels or information cards. It is possible that patients would have taken the tablets according to the regimen in practice by reminding themselves of the correct instruction with reference to the written information.

Calculating the percent of the knowledge and compliance for the total number of medicines each patient was administered may not have been the most accurate way to describe the data, due to the great variation among the number of the medicines each patient was prescribed. For instance, if a patient was on two regular medicines and was taking only one medicine regularly, this would mean that the average compliance level would be 50%, and if another patient was on ten regular medicines and was taking only five out of those ten correctly, again the patient compliance would be 50%, but if both patients decided to increase their adherence to their medication by taking another one medicine, the first patient compliance would be 100% but for the second one it would be only 60%. The same example can represent the situation with patient knowledge. This represents one of the limitations against generalizing the results in this study. The only strategy that could be employed to overcome

this problem is to recruit patients on certain number of medications but this would require a longer time to recruit a suitable sample size.

It can be concluded that, hospitalized elderly patients who received pre-discharge medication counselling supported by written information showed more knowledge of the medication regimen than their uncounselled counterparts. Post discharge counselling at home did not show a significant improvement in patient's knowledge. Ideally, all patients should be counselled about their medication before leaving the hospital in order to reduce patient errors in medication taking behaviour and improve understanding of the medication regimen. A 10% improvement in knowledge score was seen in most areas except the special instructions where a slightly greater improvement was seen. The poorest area of knowledge was side effects and this was only improved by 5% as a result of counseling.

6.4.4 Quality of Life and Nottingham Health Profile

For the Nottingham Health Profile score, counselled patients showed a lower score (better quality) for the following areas: physical mobility, pain, sleep, energy, and social isolation in comparison with the control group patients during the first assessment post hospital discharge. The scores of the different NHP areas for the two groups were kept more or less unchanged during the second assessment (Table 5.10).

There was no consistent pattern for the changes in the quality of life criteria for the recruited patients after leaving the hospital. The absolute differences in scores for pain and physical mobility between the two groups at the first visit were not large *i.e.*, only 10% and so it is unlikely that in any meaningful sense the patients would have experienced a better health status for these parameters. It would have appeared that significant and possibly meaningful differences did occur in the areas of sleep, social isolation and energy. It could be argued that the greater input in the counselling sessions and follow-up with home visits could have made some differences to feelings of social isolation. On the other hand, the control group also received home visits and an assessment before discharge. It might be concluded therefore that the reduction in medication-related problems at 10 days after discharge contributed in

some way towards a sense of well being. However, an examination of the actual medication-related problems as in section 2.3.7 does make it difficult to support such a hypothesis.

Many of the problems are concerned with issues that might not directly affect the patients' clinical condition such as medication knowledge, storage etc. rather than major issues such as the appropriateness of the regimen side effects or interactions. It is possible that some of the interface issues and differences in compliance may have had an influence on the difference in the health status of the two groups. It is also difficult to explain why no difference is seen at the second visit in what appears to be a worsening of the scores for the intervention scores and a slight improvement in the score for social isolation in the control group. Furthermore, the improvement in scores, except for sleep, for the intervention group between baseline and first home visit failed to reach statistical level of significance. All the study subjects in both groups showed a decrease in the sleeping score, which means an improvement in the sleeping pattern after leaving the hospital. This improvement was significant for the intervention patients only. A common complaint for majority of the patients was inability to sleep during their hospital stays. This may be attributed to the fact that patients were sharing the ward with at least another seven patients with different sleeping patterns and different needs which was reflected on the study subjects' sleeping behaviours. The other reason for the improvement in the sleeping pattern was the general improvement in the patients' health by the time they were ready to go home.

Comparison to similar studies is not really possible as the Nottingham Health Profile has not been used in the context of medication discharge counselling. Goodyer (1992) did examine the effectiveness of counselling given at home to patients recruited through outpatient clinics. No change was seen in the scores for the two groups, although the baseline scores were very similar in value to those noted in the second assessment in the present study. This does add weight to the evidence that the discharge counselling and liaison process in some way affected health status.

A working hypothesis might be that that a combination of fewer MRPs and interface issues and improved compliance did lead to an improved health status compared to control group at

2 weeks after discharge. It is possible that after this stage other longer term factors regarding health status unrelated to the discharge mask any influence of the medication-related issues. For instance, sleep in the control group becomes normalized and that for the intervention remains at the same level. The lack of statistically significant changes within the intervention group from baseline does tend to weaken this argument. On the current data no statistical analysis was possible to identify the relationship between these factors and the various NHP scores. This is because of the very large standard deviations observed for each of the measures, requiring large numbers of patients for statistical comparisons. For the reasons explained in section 2.3.3 the NHP was not powered to examine such correlations. These results should therefore be taken as pilot data to inform more detailed work in this area in the future.

6.4.5 Patients Satisfaction with Information Provided

Patient satisfaction is an important measure of how well services are provided and a mirror of the effectiveness of the programme adopted. It was noted that patient satisfaction is one of the important indicators of the quality of care because it reflects whether or not the given service is meeting patients' expectations and is consistent with their values (Kucukarslan and Schommer, 2002). The *Satisfaction with Information about Medicines Scale* (*SIMS*) was therefore developed, validated and piloted (Horne *et al.*, 2001b).

Results in Figure 5.6 suggested that, in general there was a very high level of satisfaction with the service provided to the patients of the intervention group before and after hospital discharge, *i.e.*, study subjects of the intervention group showed a significantly higher level of satisfaction with the information provided. Patients of the intervention group scored a median of 9 on the *SIMS* in comparison with a median of zero for the patients in the control group. These results differ from those found in a study by Patel *et al.* (2002) aimed to compare patients satisfaction with their medicine information and beliefs about medicines between groups of patients who did and did not attend an education clinic provided by a rheumatology specialist pharmacist. The *SIMS* tool was used to measure patient satisfaction with the information they received about medicines. Although this study was not randomized, there was no significant difference in the patient satisfaction between the two groups where

patients in the clinic group scored a median of 14 and those in the non-clinic group scored 12.5. No definite explanation was given for the similarity between the two groups in *SIMS* score, but it is clear from the high scores reported by the control group (12.5) that the patients were already satisfied with the information which means that the education clinic did not add very much to what already patients knew regarding their medication.

Patients of the intervention group were least satisfied with the information provided about how to tell if the medicine is working, how long it takes to show an effect and how long they need to be on that treatment. Most of the patients in both groups were surprised to be asked about the effect of the treatment on their sexual function and a few were embarrassed to be asked.

No apparent relationship between patients satisfaction with the information they received about the prescribed medication and either the quality of life or adherence to the drug regimen was shown. This may be attributed to the fact that many of the patients had been taking medication for many years and their adherence pattern was influenced by the long-term use rather than the satisfaction or dissatisfaction with the information. These results differ from the findings of Kendrew *et al.* (2001), which measured satisfaction with information in patients with chronic pain. In this study the *SIMS* questionnaire was used to assess the degree of satisfaction with the information. Patients with chronic pain (average age of 54 years) were most satisfied with information about obtaining a further supply, how to use their medication and its purpose. Self-reported adherence was significantly related to satisfaction with the information provided. In this pilot study, patients from the general population were assessed and it focused on only one category of patients (patients with chronic pain).

Intervention group considered counselling sessions and the written information provided to them to have been helpful. Many of the patients expressed their appreciation that someone was keen enough to provide them with such information. Patients of both groups were particularly appreciative of the follow-up service they received, as it showed that the hospital was still caring about their health, even after they had been discharged.

Because the investigator who performed the patient counselling was the same person administering the *SIMS* questionnaire, it has to be taken into consideration that this might have influenced the views of some of the participants and their desires to please the investigator. It was difficult to ascertain whether the questionnaire measured satisfaction with the programme per se or alternatively with the key role played by the investigator in the delivery and the management of the programme. This limitation is common to many patient satisfaction questionnaires and the only solution to overcome this problem is to have another blind interviewer to administer the questionnaire. Due to limited resources it was difficult to employ another investigator and the researcher had no alternative but to administer the questionnaire herself. In spite of this potential bias, the great difference in patients' satisfaction between the control and the intervention patients probably shows a real satisfaction and demonstrates success of the education sessions provided to the intervention group patients. The other weak point regarding using *SIMS* in this study is that the score is normally calculated for each medicine but because of the fact that the patients in this study were taking an average of 8 medications it was difficult to administer the questionnaire for every single medicine. Therefore, a single administration to express an average satisfaction score for the information about the whole lot of medication patients were taking was performed.

6.4.6 Identification and Classification of Medication-Related Problems

This study aimed at identifying MRPs in the elderly and classifying them to resolve or prevent such problems. Using a non-structured face-to-face interview was an important element to identify MRPs in this study. The extent of use of medicines seems to be high as expected in this population and the use of prescription drugs seems to be associated with substantial incidence of medication-related problems. On an initial assessment for all types of MRPs, 16 categories of MRPs (Section 5.3) were identified with a total of 226 problems in both groups during the first home visit with an average of 2.3 (S.D= 1.56) MRPs/patient. This number went down to 152 problems during the second visit with an average of 1.92 (S.D= 1.25) problems per patient.

The finding of an average of 2.3 MRPs/patient is lower than those reported in other studies using the same methods. It must be stressed on the fact that, this level of problems does refer to that found at two weeks post hospital discharge and not problems concerned with medication at the point of discharge, which for the purposes of this study were considered as zero. For instance, referring to table 5.13 the classification inappropriate drugs, inappropriate duplication of therapy, contra-indication and no clear indication means that in the main that the patient was taking old stocks of medicines they had at home and do not refer to the discharge medications. Also, the cases referring to the drug dose to low/high actually mean that either the patient was self-medicating with an inappropriate dose or a GP prescription may not have been appropriate.

In a study carried in the British Virgin Islands (Titley-Lake and Barber, 2000), where a comprehensive medication review was carried out on 50 elderly patients, there were 5.9 problems/patient. In another study carried in USA on 53 non-institutionalized elderly patients, there were 11 potential problems/patient (Shimp *et al.,* 1985). The low average of the MRPs reported in the present study may be attributed to the fact that patients in this study were recently discharged from the hospital and were stabilized on the medication they were prescribed. Another reason for these variations in the average number of problems per patient from one study to another is the variability of the definition of the MRPs employed in each study and the variability of the classification being used to screen these problems, in addition

to the use of structured questionnaire as a tool of identifying the different MRPs. The different sittings from where the patients were recruited can cause some variation, as the patients of the two other studies were recruited by using social services records as the main source of identifying the patients. Different community with different medication pattern may be another factor. In Shimp *et al.,* (1985) the social drugs (smoking and alcohol) were also included in the screening process. Finally, the limited clinical experience of the investigator compared to that of the clinical pharmacist or an expert panel used to identify the problems may be another contributing factor. This is an important point as the investigator was an overseas pharmacist with relatively little clinical experience. Before undertaking the project she was trained to UK graduate level in clinical pharmacy by joining the final year module at King's College London on that subject. In addition, she took some part time work as a pharmacy technician. Therefore, the clinical competence must be viewed as that of a newly qualified pharmacist or technician. The advantage of this is that the system was assessed assuming the minimal level of seniority involved with the delivery of the service, which has large implications for the cost of such a service. The researcher did however refer any clinical decisions to the clinical supervisor at St.Thomas' hospital.

The 16 categories developed in this screening were not designed to be a definitive set of categories, but aimed to integrate all the types of MRPs identified.

As mentioned previously, two different classification systems were employed in this study. The PCNE system was chosen because of its ability to classify both the causes and the interventions related to the identified problems. Also, this system is more detailed in pinpointing a broad range of problems due to large numbers of sub-categories included in this system. The PCNE system cannot assess the problems according to the degree of clinical severity and for that reason a minor, moderate and severe classification was developed. Some of the identified problems did not have direct clinical impact on the patients and could not be classified according to a severity scale or even according to the PCNE system. While the PCNE system has already been validated, the second system was introduced solely for the purposes of this study and the reliability of this system was confirmed as part of this study.

6.4.6.1 PCNE Classification

This hierarchical system comprised separate codes for problems, causes and interventions. According to this system, MRPs are defined as "*an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes*" (Van Mil, 2003). Up to the time of writing this section and after searching the internet using the full Medline database through PubMed, Pharm-line website, RPS ePIC Database and the PCNE website, there has been no published article concerning the use of the PCNE classification system in UK, or using PCNE classification system for classifying of the MRPs identified in elderly patients recently discharged from the hospital.

This system depends mainly on classifying the identified problems on the basis of the problems, their causes and the interventions suggested solving these problems. After identification of the different problems, each problem was given a code according to the PCNE codes. Most of the problems were clear enough to be coded using the system codes, but some of the problems failed to be categorized under any of the system problem classes (*e.g.*, using expired medications and storing the medicines under the sink in the kitchen). For these problems, the investigator had to classify them under the category "***others***". This problem arose because the system was based mainly on problems with clinical effects.

Some problems could be classified under more than one problem code, in these situations, the system designer (Van Mil) was consulted by sending him the different cases and a common code was reached between the investigator and the designer.

Because each patient may have more than one problem for the same medicine, and also may have the same problem because of more than one medicine, classification was performed on two bases, according to the number of the problems identified (whether for the same medicine or not) (Table 5.13) and according to the number of patients suffering from certain problems (Appendix XXII).

Table 5.13 gives the best summary of the clinically-related MRPs and the effect of the intervention. Study subjects of the control group had a higher incidences of MRPs than the

patients of the intervention group, and this finding was observed during both the first and the second home visits which indicates the importance of introduction of the pharmacist-initiated drug regimen review.

Insufficient awareness of health and the disease was the most common group of problems patients in the control group suffered during both the first and the second visits. The percentage of knowledge-related problems decreased significantly in the intervention group from the first visit to the second visit. During the second home visit, the percentage of this problem in the control group was almost three times higher than that in the intervention patients. This difference could be attributed to the education and counselling sessions patients of the intervention group received prior to hospital discharge and was reinforced again during the first home visit.

Side effects have a relatively high incidence, surprisingly, higher in the patients of the intervention group during both visits (22.6% and 24.6% respectively) and no obvious change was observed between the first and the second assessments. A likely explanation is that this group has been educated and received information regarding side effects which may have affected their beliefs about the occurrence of these effects, facilitated recognition of such effects and made them more likely to report them. Providing patients with information regarding side effects was a sensitive issue as it is widely believed that patients may wrongly claim to have certain side effects if they receive any warning about them and this may affect their compliance. Shimp *et al.* (1985) carried out a study in the field of MRPs and offered two valid reasons why side effects in the sample he was studying remained high. First, the nature of the symptoms may cause many side effects to be mistaken for symptoms of medical illness, and, second, the likelihood that a patient will experience side effects is increased as the number of possible offending agents increase. Also, counselling itself may raise patients' awareness of side effects.

These results were similar to those reported in a preliminary analysis of 321 medication-related problems identified by Paulino *et al.* (2002) in 189 patients recently discharged from the hospital. The nature and the frequency of MRPs for recently discharged patients in

community pharmacies in different countries (Austria, Denmark, Germany, Netherlands, Spain and Portugal) were examined. Structured questionnaire was used where the pharmacists documented the different interventions performed. The most commonly identified problems were uncertainty or lack of knowledge about the medication and side effects. Because it was only an abstract, no further details were provided about the nature of the problems or the details of the interventions performed to solve the identified problems.

Many problems such as inappropriate drug/form, drug choice, contraindication, interactions and therapeutic failure showed a very low incidence. This low incidence of clinical problems can be attributed to the recent hospital review of medication and good attention to pharmaceutical care prior to discharge. The higher percent of the absence of a clear indication for the medication administered the problem of wrongly prescribed drug and the dosage problems among patients of the control group are also reflection of the interface issues. They could be attributed to the poor communication between the primary and secondary care professionals as many of the GPs were not aware of the changes to patients' medication during their hospital stay, which resulted in repeating the old prescriptions or not prescribing the new medicines during the hospital stay.

The PCNE classification system represents one of few systems which have the options of classifying the causes separately. According to the PCNE classification more than one cause can be assigned for each problem. A total of 255 causes (Table 5.15) were reported during the first home visit (average of 1.06causes/problem). This total decreased to 171 causes during the second home visit (1.05causes/problem). The "*manifested side-effects*" were the main cause behind the identified problems in both groups (14.3% in the control group and 20.7% in the intervention groups). This was followed by "*unknown instructions of use and/or administration of the medication*" and then "*lack of communication between health professionals*" in the control group.

Poor knowledge of use of medication and lack of communication between healthcare professionals were the two main causes behind the problems in the patients in the control group during the second home visit. This finding demonstrates the importance of the

patient's education after discharge from the hospital and the interface liaison between the primary and the secondary healthcare professionals which was offered to the patients of the intervention group.

While the 240 detected drug therapy problems during the first home visit generated a total of 97 interventions, the 166 problems identified during the second home visit generated only 26 interventions which were grouped into 10 categories (Table 5.17). It was very difficult to report the interventions performed for the patients of the control group and the only source was what the patients themselves reported. All the interventions performed by the investigator were performed by oral information in all the study group patients. It is obvious that one type of problems may lead to several kinds of interventions. As mentioned previously, to avoid ethical dilemmas, the investigator reported potential serious problems identified in the control group to senior clinical pharmacist in the Elderly Care Unit in St. Thomas' Hospital.

Two categories of interventions were dominant "*patient medication counselling*" and "*prescriber informed only*". ' vement in patient understanding of the therapy" which is quite similar to "*patient mea* n counselling" reported to be the main intervention in a study by Anderson *et al.* (20(n this study, pharmacy staff in randomly selected Swedish community pharmacies used a f-reporting system to register the number and the type of the interventions made in relation to medication-related problems. In the Anderson *et al.* study, the MRPs and the corresponding interventions were grouped in relation to the prescribed medicines, OTC medicines and persons seeking advice without buying any medicines.

Informing the prescriber of MRPs is the second most important intervention and about 34% (17/50) of the intervention group patients required such contact at the first home visit. This represents the scale of problems attributed to interface issues. There are two inferences to be made:

1. The contact resulted in a significant reduction of problems as on the second home visit as the prescriber needed to be contacted on only four occasions.

2. The system of passing information to the prescriber on discharge was not adequate.

Interventions of low frequency fell under the category ***others*** and interventions performed at drug level. The PCNE system did not provide special category for interventions at the pharmacist's level so all the interventions involving the community pharmacists were categorized under ***others*** and this was recorded in only four occasions (three during the first home visit) where the investigator needed to contact the pharmacist for clarification. One pharmacist was contacted to dispense 20mg Frusemide to be taken once a day rather than half tablet of the 40mg. Another pharmacist was contacted to inform him of the wrong strength of inhaler dispensed. The third pharmacist was contacted to arrange delivery of the medication to housebound patient and finally to report that a wrong antidepressant was dispensed.

One of the aims of this study was to liaise with the community pharmacists and to involve them in the medication management process, and although most of the pharmacists who were contacted by the investigator stated that they would like to receive relevant information about patients attending their pharmacies when discharged from hospital, a weak response was noted during the study. Three community pharmacists only interacted with the researcher, two during the first home visit. In two cases the community pharmacists contacted the investigator to clarify and confirm the changes to a patient's medication post hospital discharge after they received a copy of the TTO with the new discharge medication. The third case was a home visit made by the community pharmacist to his patient to check discrepancies in the strength of the Beclomethasone inhaler he dispensed and to supply the patient with the correct one. The investigator phoned this pharmacist to inform him about the discrepancies between the strength of the inhaler prescribed and that already had been dispensed.

These findings would lead to the conclusion that the community pharmacists seldom participate in the process of medication review and medicine management for patients recently discharged from the hospital, although they were contacted by the investigator as early in the discharge process and were given the chance to intervene by sending them copies

of the TTOs and the other information they may need to monitor the difference between hospital discharge information and GPs' prescriptions. This may be due to insufficient time for the pharmacist to contribute in this process or obtain the funding to provide other services (Bellingnan and Wiseman, 1996). It can be also concluded that the main contribution to the differences in the interface issue between the control and the intervention group occurred mainly due to better liaison with the GPs rather than community pharmacists.

PCNE as a system was used in this study to illustrate the effect of pharmaceutical care and medication review on lowering the number of the identified medication-related problems between the intervention and the control group as well as indicating where interventions have been made to resolve these MRPs.

6.4.6.2 Medicine and Service-Related Classification

As mentioned previously (Chapter 2), the medicine and service-related problem classification system is a novel system inspired from another classification used in studies carried out by Dean and Barber, (1999) and Gordon *et al.*, (1999) and was adopted in the present study to assess the importance of MRPs. There is no published evidence that this classification has been used previously in the same context. In this classification system, medication-related problems are classified into two major classes according to their sources: those with medicine-related effects (depending on the degree of severity) and those with services-related effects. Each class is divided into various subclasses and each subclass was given a score which was used to weight the medication-related problems quantitatively. In the medicine-related category, the minor, moderate and severe scale was used. One of the advantages of using this scale is the premise that the scale is simple to use if there are large numbers of MRPs for which the significance needs to be measured; this is in addition to the fact that this scale enables the investigator to measure the severity of the identified MRPs (Balestrini *et al.*, 1999).

It was found that the two groups (control and intervention) had equal numbers of patients suffering from the medicine-related problems during the first assessment, but after reviewing

the intervention patients' regimens, this number decreased to almost half during the second home visit (Appendix XXIII).

When the patients of the two groups were compared for the number of identified MRPs in each class, it was found that the total numbers of problems discovered was higher in the patients of the control group compared to the intervention group during both home visits and this supports the results obtained from he PCNE system. When the average number of the identified problems was calculated, it was found that the average of the MRPs identified in the patients of the control group was higher than that identified in the intervention group (1.74problems/patient vs.1.48problems/patient) during the first home visit. The average number of the problems decreased by almost a third for the patients in the intervention group (0.98 problems/patient) while moving from the first to the second home visit.

This dramatic decrease may be attributed to the significant decline in the number of the moderate problems identified in the intervention group from the first to the second home visit. Patients of the intervention group showed less severe problems during the first home visit compared to the control group. This may be due to the immediate communication between the investigator and the GPs which may have given them a chance to overcome errors. During the second home visit, the number of the severe problems was almost the same for both groups; this would confirm the explanation given above, as GPs of the control group patients needed a longer time to receive any changes made to their patients' medications.

The second class of this system is the "service-related problems". Any problem identified can be classified under both medicine and service-related problems. The average numbers of identified problems for all the patients in both the control and the intervention groups during the first home visit were 1.73 problems/patient and 1.44 problems/patient respectively. The average number of problems in the control group (2.07 problems/patient) was almost double that identified in the intervention group (0.9 problems/patient) during the second visit (Table 5.19).

Results show that patients' knowledge and compliance were the two main problems for patients of both groups during the two domiciliary visits. While the number of knowledge problems identified in the intervention patients decreased significantly, the compliance issues did not show the same dramatic decline pattern. This finding confirms the absence of a positive relation between patients' knowledge and adherence to their regimens. In this study, intentional and unintentional non-compliance (forgetting to take medicines) were analysed together as one problem because patients do not normally admit their intentional non-adherence. Berardo *et al.* (1994) identified a high proportion of compliance/adherence problems in elderly patients who were interviewed about their medications. Similar results were reported by Schneider and Barber, (1996) and Foulsham and Goodyer, (1999). Several reasons for poor adherence emerged from the home visits including: forgetfulness, poor understanding of dosage instructions, fear of the danger of addiction or dependence or side effects, loss of confidence in the efficacy of the medicine or belief that there is no need for the medicine.

Physical problems were defined as any personal difficulties that may have affected managing the medication effectively. This category included patient's ability to obtain the medicines from containers or packs, to use the inhalers properly and sight problems which may affect reading labels. There were little differences between groups in the level of physical problems during the six-week period of the study.

Interface issues are any problem demonstrated due to poor communication between the primary and secondary care units. This can result in reissuing of a previous prescription when the drugs may no longer be required or have been changed, or not prescribing a new therapy initiated in the hospital. Some issues are also related to the lack of monitoring illness or reviewing medicines. During the first home visit, interface problems in the intervention group were about half of those identified in the control group; this emphasizes the importance of communication between the different healthcare professionals in the different settings (Tables 5.19 and Appendix XXIV).

One of the interface issues reported in this study was the absence of clear explanations for medication changes from the hospital, leading to patients reverting to pre-admission medication. Although GPs and community pharmacists were informed about the study and the change to their patients' medication, six patients (Appendix XXIV) of the intervention group had interface issues during the first home visit and the GPs were contacted again by phone to report these changes. The number of patients with interface issues decreased in both groups during the second home visit to almost the same for both groups. For the intervention group this may be due to the phone calls made by the investigator to confirm the changes happened. For the control group patients this may be attributed to the letters sent by the hospital which may take more than two week to reach the GPs. These results may indicate that such problem can generally be resolved post discharge but can be prevented by good and prompt communication between the secondary and primary care settings immediately post hospital discharge.

Another interface issues involved different brands of the same drug being used which could result in patients taking both not realizing that they were doubling the dose, *e.g.*, one patient was taking Diamicron before his hospital admission and on discharge he was prescribed the generic Gliclazide, resulting in the patient was taking both as two different drugs for diabetes.

The third interface issues reported in the present study was reusing (not re-prescribing) discontinued medication. One patient was taking Frumil before being admitted to the hospital and this was stopped as it contributed to her fall which resulted in her hospital admission. Although Frumil was stopped and the GP did not re-prescribe it, the patient insisted on using the old stock she had at home and her excuse was that the GP had not informed her about this change and she would not stop anything without consulting the GP. The investigator phoned the GP to confirm the changes which he was already aware of (through the letter sent to him by the investigator) and to inform him about the importance of re-counselling the patient regarding the changes that happened to her medication. All these examples demonstrate the need to provide the GPs with the information on drugs on discharge, supply, dosage or strength changes or discontinuation of certain medication which in turn would help smooth

the process of transfer of the patient from the secondary to the primary care. This confirms what Sexton *et al.* (2000) reported: "*Effective communication between the secondary and primary care is essential for safe and successful prescribing of medication therapy post hospital discharge*". Lack of such communication may lead to inappropriate prescribing, change of formulation or unintentional discontinuation of therapy (Duggan *et al.*, 1998).

As mentioned previously, although pharmacists on both sides of the interface showed enthusiasm to improve communication and to facilitate medicine management across the interface, little was offered by the community pharmacists who were given the chance to intervene. This may encourage the introduction of primary/secondary care interface pharmacists. This role has already started in some hospitals and primary care trusts, *e.g.*, Kensington and Chelsea PCT and Hull Royal infirmary where the pharmacist spends half his/her time working on interface issues and the other half as a clinical pharmacist (Bellingham, 2004).

All the above mentioned issues suggest that patients are at risk of problems concerning their medication when they move between care settings and lack of communication can be one of the factors underlying this problem The possible solution to overcome these problems would be to follow-up patients after discharge into the community to identify any discrepancies and liaise with GPs.

There was a significant decline in the percent of the identified problems among the patients receiving medication review (intervention) and this again cross validates the PCNE system, where domiciliary visits can strongly reduce the percent of the MRPs identified in primary care. It was difficult to compare the results obtained in this study with other studies because of the differences in the classification systems applied.

A weak point of this section is the fact that the process of identification of the MRPs depended mainly on an observational experience and non-structured patient interview which is more subjective and may be a source of bias. A more structured interview should be designed to guarantee the consistency of the process of identifying the MRPs.

To ensure the usability of this classification system, the reliability of the system was measured using inter-rater reliability where more than one investigator or rater was involved in assessing the new system and the degree of agreement between the two raters is assessed. This was performed by a second assessor independently rating the problems identified. All the identified problems were written down as a blind electronic copy (Appendix IX) and handed to the second investigator with a copy of the different codes to be used in this coding process.

After measuring all the outcomes, and comparing these outcomes during both the first and the second home visits, it would be useful to mention that most of the improvements were reported during the first home visit rather than the second visit, but it was important to conduct the second home visit to report the effects of the interventions conducted during the first assessment, as most of the identified MRPs were intervened during this assessment and the results were noted during the second assessment. Because of the time limit of this study, each patient was reviewed over a period of six weeks from the day of discharge although the National Service Framework for Older Patients recommended that all the patients aged 75 years and over should be reviewed annually and those on four or more medications should receive a biannual review. As the average age of the patients in this study was over 75 and the average number of medication was 8 medicines/patients, so all the patients should receive a third home visit six months post hospital discharge.

6.4.7 Comparison to Other Similar Studies

Direct comparisons of the results to UK studies concerning discharged medication is not straightforward as most have focused very specifically on interface issues. From the previous discussion it does appear that the range of MRPs after discharge are very much the same as might be expected in an elderly population, many relating to patient understanding, coping with complex medicines and using medication no longer prescribed. However, the range of true clinical problems was less in certain categories. For instance, Foulsham and Goodyer (1999) found that 20% of patients visited had drug choice problems compared to only 1-2% in the present study. Similarly, 60% had administration problems compared to 22% in the present study. Even knowledge-related problems were at a lower level with 60% in the

Foulsham and Goodyer (1999) study compared to 50% in the present study. This is probably related to recent discharge, in that patients will have a higher degree of awareness of medication issues whilst in hospital and that clinical and administration issues would have been reviewed and resolved in a higher proportion than those not recently discharged. Therefore, no detailed comparisons will be described in this section concerning MRPs in general within the elderly population. There now follows a more detailed examination of this issue related to UK discharge schemes focusing mainly on the interface issues.

Coleman *et al.* (2001) assessed errors in discharge advice notes and transcription errors to the GP prescribing systems. If the assumption is made that these would eventually translate into prescription errors then a comparison to the control group during the first home visit can be made. They noted an overall level of such problems as 12% in their study, half the level in the present study. The types of problems were similar to those described in Appendix XXVI. In terms of old medication not stopped this was 2% compared to 10% in the present study, for prescription not changed 3% *vs.* 6% and incomplete list from the hospital 1% *vs.* 2%. One point not reported in the Coleman *et al.* (2001) study is the situation where the hospital had failed to note regular medications on admission which was an element in 4 cases in the present study. This is an important point as there were fewer cases due to this in the intervention group. It is probably a result of information sent to the GP/CP in the intervention group resulting in a review of the patient's medication, and the advice to patients to discontinue any medications taken before discharge unless specifically on the discharge medication list. The much lower incidence of interface issues is probably due to the Coleman *et al.* (2001) study involving younger patients on less complex regimens.

Burns *et al.* (1992) simply classified their interface issues concerning the elderly as to whether the GP had made an addition or omission not intended by the hospital, this form of classification also included items added but which the hospital were unaware on admission. Of the prescriptions issued 2 weeks post hospital discharge 30% had additions and 22% omissions. If classified in the same way, the present study would give a value of only 4% omissions and 22% additions. This is probably because the Burns *et al.* (1992) study calculated the percentage of patients with new prescriptions, whereas this was not assessed in

the present study and the calculated values of 4% and 22% assume that all patients had a new prescription at 2 weeks. This may not be the case and the data was not recorded. The finding is consistent in that the additions reported were either what was intended or known to the hospital before discharge were a bigger problem than omissions. This trend seems to be confirmed by Cochrane *et al.* (1992a) where they identified 20% of patients had a drug stopped compared to 40% having a new drug on returning home. This very high rate of new drugs included logical drug substitutions, such as generic/proprietary changes and changes for new conditions since discharge not included as problems in the present study.

The intervention group on first visit had fewer interface issues than controls comprising of just 12% of patients. This consisted of 3 patients where an old drug was re-prescribed, 3 where medication had not been reported on admission and one dose change (Appendix XXVI). It does appear that the improved communication and possibly discharge counselling reduced the incidence of such issues. This seems to be somewhat better than the intervention by Binyon (1994) which involved pharmaceutical care plans and 16% were still taking unintended medication. They did record a large number of discrepancies as a result of a change in dosage instructions *e.g.*, one in the morning to one daily. This did not seem to be a common problem in the current study and may be a result of the fairly recent widespread introduction of computerized GP prescribing systems.

Pickrell *et al.* (2001) study did not report the details of discrepancies as a result of the seamless care study, but the overall level was 11% of drugs in the intervention group, a considerable reduction compared to 70% in controls. However, this involved just 15 patients in each group and included minor discrepancies such as generic/proprietary changes.

The question of the actual impact of discrepancies was investigated by Duggan *et al.* (1998) where a panel judged the importance in a group receiving a seamless care package. Overall, 32% in the intervention group and 52% in the control group had some kind of discrepancy. This was judged by the panel as just 1.6% in the intervention and 3.2% in the control group as having a definite adverse effect on the patient. It is therefore likely that the figures reported in the present study would be judged to be lower in terms of clinical significance.

This must be taken in the context that Duggan *et al.* (1998) included more categories of minor discrepancies than the present study.

Smith *et al.* (1997) observed a very high number of discrepancies in their study of around 50%, although again the criteria for judging them are not clear. They found no difference in the intervention group in which information was supplied to the patients to pass on to the GP or community pharmacist. This is different to the present study where information was sent directly. A-Rashid *et al.* (2001) study reported discrepancies in 25% of patients in the control group at first home visit compared to 5% in the intervention group. The study was similar to the present one but they did not report discrepancies at the second visit.

In summary, it is quite difficult to compare levels of interface issues across the different studies due to the very different criteria set to judge such problems. The system used in the present study really only examined issues where a drug should have been discontinued, was omitted or the hospital was unaware on admission. There is a broad agreement with other studies that as assessed two weeks after discharge the interventions do reduce such problems. It may have also been useful to have gathered data on more minor discrepancies such as propriety/generic name changes. No other study seems to have examined the impact of the domiciliary visit on resolving interface issues, but the findings in this study was that six weeks after hospital discharge most cases had been resolved with or without an intervention.

In terms of MRPs in general the findings agree with others that there are a considerable range and numbers that benefit from a domiciliary visit, but the taking of old medications discontinued by the hospital is a specific issue for the recently discharged patient and may be helped by a visit soon after discharge

6.4.8 Inter-rater reliability

All the identified MRPs were independently rated by two raters and the test-retest reliability was studied by calculating the degree of agreement between the two raters for each category during both domiciliary visits using the intra-rater (Kappa Coefficient **κ**). The kappa coefficient is used where 2 observers classify cases according to whether some finding (in the

present study, an error) is present or absent. It was more convenient to perform this test on each category separately rather than performing it on all the categories simultaneously using one 10 X 10 matrix. This may be attributed to the variation in the number of cases in each category. Also, it was more accurate to perform the test on each study group separately to find out if there was any bias from the main investigator during the process of rating as she was not blind during this process. There is no value of Kappa that can be regarded universally as good or poor agreement but a general guideline (Table 4.1) can be used for interpretation of its values. The raters showed a substantial level of agreement when they rated the severity of the identified MRPs. According to Landis and Kock (1976), the strength of agreement associated with Kappa coefficient between 0.8 and 1 is almost perfect and substantial between 0.6 and 0.8. The degree of agreement between the two raters varied between fair to very good for both the first and second home visits with regard to the medicine-related category with an average of 0.53 (moderate). For the service-related category, degree of agreement varied from moderate to very good (Table 5.19) with an average of 0.78 (good agreement). Although arbitrary, these divisions provide useful benchmarks for discussing the relative strength of agreement between raters. In the light of these categories, the present results show that the two raters were able to use this classification system with a substantial level of agreement (on average) and moderate to very good as the degree of agreement between the two raters for the intervention group suggests that the main investigator was not biased during the coding process.

Due to limited resources, the second rater was the main supervisor of this study which may be a potential source of bias. The only approach being adopted to overcome this potential bias was to offer blind data to the second investigator (the second rater was not aware which patient was control and which was intervention) and the moderate degree of agreement results do not suggest any source of bias introduced. The main source of variation between the scores of the two raters is likely to be related to two factors: firstly, the variation in the clinical experience between the two raters and secondly, the subjective nature of the classification system makes it difficult to get a perfect degree of agreement. Finally, the variation in the interpretation of the problems is due to variation of the sources from which raters obtained their information about the patients' problems. The first rater who is the main

investigator had direct contact with the patient and with the problems they suffered and she was the one who recorded all the problems and summarized them, while the second rater classified the problems according to the written details provided to him. To overcome this problem, it would be useful if all the home visits were audio-recorded. Also, it would be useful if an expert panel can be elected to carry out the process of the rating or at least to have a third party sharing in the process of rating. The other recognized approach is the use of a panel to judge the nature and severity of such problems as has been used by a number of other studies (Duggan *et al.*, 1998 and Dean and Barber, 1999). This was outside of the resources of this study.

The final message is that a single coefficient (such as kappa) is not necessarily a complete description of the relationship between the judgements made by 2 raters. Feinstein and Cicchetti (1990) proposed separate indices of positive and negative agreement, and demonstrated that kappa is a weighted sum of these 2 quantities. Using 2 indices can reveal, for example, that judges agree about the absence of an error, but not on its presence. This approach may be seen as analogous to the use of 2 indices, sensitivity and specificity, to evaluate the performance of diagnostic tests. It is believed that broader use of the 2-index approach to inter-rater reliability is warranted.

6.5 Rate of Hospital Readmissions

Out of the 122 recruited patients, 53 (43.44%) were readmitted to the hospital at one or more points during the period of this study (six months). Nine patients (7.4%) were readmitted to the hospital due to MRPs. This percent is less than that reported in Col *et al.* study (1990) where 28.2% of the 315 interviewed elderly patients were admitted to the hospital because of MRPs. Three (2.5%) cases (one in the intervention group) were related to ADRs (the intervention patient had bleeding due Warfarin and vomiting due to Digoxin. the second patient had a fall due to diuretics and the third was admitted because of diarrhoea secondary to Antibiotics used). This finding was less than that (6.3%) found in the Lindley *et al.* (1992) study, where the extent to which ADRs in elderly patients admitted to hospital due to inappropriate prescribing was determined. Warfarin was one of the medicines most often implicated in adverse drug reactions hospitalisation in the Col *et al.* study (1990). Another two drug-related hospital readmissions (one in each group) were due to therapeutic failure (angina was not controlled in one patient, and the hypertension was not controlled in the second patient). The remaining 4 cases (1 in the intervention group) were correlated to patient's non-adherence to the treatment regimen (3 cases were exacerbation of COPD due to underuse of inhaler or nebulisers, and 1 case was admitted because of pulmonary oedema secondary to drug omission).

There was no significant difference (Table 5.21) between the two groups with respect to the number of hospital readmissions and the number of patients readmitted during the period of six months. It was difficult to carry statistical analysis on the number of admissions related to medicines between the two groups but it was clear that there were fewer drug-related readmissions among the intervention group which indicated that hospital discharge planning and patient's education may have positive effect on reducing rate of medication related hospital readmissions.

As a final summary of this project, it can be concluded that, hospital discharge counselling and a follow-up visits at home post hospital discharge, would ensure that the correct medication is being used and the medicines left at home have not been restarted. Compliance and patient knowledge could be rechecked and any medication-related problems experienced could be monitored and solved.

6.6 Strategies to Limit Research Bias

This section will discuss three areas of potential bias associated with the present study; selection bias, observer bias and participant bias. Some of these areas have been mentioned in other sections in the context of the study limitations. They will be considered in terms of a description of the sources of the bias and steps that have been taken to limit such bias as well as the reasons why any of such limitation could not be easily undertaken.

6.6.1 Selection Bias

This may occur when the characteristics of any group differ sufficiently from the other, such that they would have a chance of showing differences between them in terms of the various outcomes at the baseline. The other aspect of selection bias is that the subjects are not representative of the general population, so limiting the application of the results of the study. There is also concern that unusual characteristics of the bias selection are not fully identified.

The selection process of subjects in this study depended to a large extent on the resources available to the researcher. The project was time and resource limited and dependent upon a single researcher. This meant that a single site only could be used and recruitment process performed within the time available to the researcher. To limit any selection bias, the whole population of elderly patients meeting the inclusion criteria (Section 4.5.1) was approached for inclusion. This meant that patients were not just approached from the care of the elderly wards but also from the other general medical wards. It is also possible that if the researcher was only available at certain fixed days then a selection bias of the type of patients discharged on those days could have occurred. Therefore, care was taken from the researcher to be available whenever discharge was planned Monday to Friday every week.

By the preceding comparison to other studies, no particular selection bias seems to have been identified. As described in the earlier sections of the discussion, the age range, sex distribution, range of chronic diseases and medication does seem to be similar to elderly populations previously studied regarding medication discharge. The number of discharge medicines seems to be higher than some others but this does seem to apply to elderly patients with chronic condition at the hospital site. From what is proven regarding general levels of compliance, medication knowledge and type and numbers of medication-related problems,

there does again appear to be no major differences to other similar studies. It is therefore, safe to assume that no selection bias in this respect has been introduced.

The standard approach to ensure selection of matched groups for comparison is by randomization as was performed in this study. Again, there does not appear to be any major differences between the two groups in terms of the baseline measure taken before intervention. One of the NHP measures did statistically differ although it is hard to justify the impact of the differences in terms of the various outcome measures. It is also unfortunately clear that compliance could not be measured before any intervention. A tablet count could not be performed in the hospital, but the study particularly encompassed pre-discharge counselling. It is possible that one group was an inherently "different complier" to the other, though there is no reason to suppose that to be the case.

6.6.2 Observer Bias

The study was not blinded in any respect and would be expected to be a source of number of areas of bias as group allocation was known to the observer. It has to be pointed out that even if a blinded observer visited subjects it is possible that they would become aware of group allocation. For instance, a participant may well describe the counselling session when being administered the knowledge questionnaire. The only way to limit much of the observer bias may be introduced within the limited resources of the study was to ensure a standardized approach to the assessment process and minimize observer's judgments concerning the range of quantitative data gathering.

The knowledge questionnaire was structured such that correct/ incorrect responses were recorded. It would have been preferable if the questionnaire was self-administered but this proved not to be possible in view of frailty of many of the participants and response rate would have been poor. The impact of the counselling session does appear to be similar to other studies as discussed earlier in this chapter.

Tablet counting is an objective measure and the results obtained were so similar to other studies, both blinded and non-blinded. It is reasonable to assume that this was not a major source of error in the compliance assessment process.

Both the NHP and the *SIMS* are well validated questionnaires that require no judgment by the interviewer in recording responses. There is no reason to suppose any suspected observer bias to be introduced, but this can not be ruled out and only avoided by blind assessor.

There are some potential areas of observer bias associated with the identification of various MRPs, much relied on the investigator identifying particular problems associated with the patients' medication. It is possible that, another rater may have not recognized such problems as being presented or perhaps noted additional ones. Further more, the investigator may have been biased into reporting a greater number of problems in the control group and less in the intervention group. This was minimized by having a second blinded rater reviewed all of the cases and recorded judgments according to the classification system being used (section 2.3.7). In order to accomplish this, all the cases were recorded in a standard format identifying the medication list, medical condition as known on discharge and general findings on the home visits. This does still rely on the observation of the main investigator. For instance, to record the judgment of a MRP being an 'inappropriate dose' the researcher might recorded 'patient taking old stock of medication at different dosage to that on discharge' and introducing a potential source for bias. On the other hand, for areas such as drug interaction, contraindication, no explicit statements needed to be made by the investigator.

In conclusion, within the limitations of the present study, some of the observer's bias was unavoidable. However, consistency of results with other similar studies might suggest this to be minimal.

6.6.3 Participant Bias

There are a few areas where participant knowledge of the assessment may bias their responses. One of the most important in this study concerns the assessment of compliance via tablet counts; where study subjects may be tempted to remove tablets just before the home visits in a trial to mask potential non-compliance. This can be minimized by not making the subjects aware of the tablet counting process. This was achieved by Raynor *et al.* (1993), where tablets were removed for latter counting and subjects were told that was being done to provide them with a fresh supply. Such an approach could not be adopted in this study as it

was the intention to record GP issued prescriptions to examine interface issues. However, it was not mentioned specifically to the patients the purpose of the tablet count. When patients were asked to show their medication, the explanation given to them was to record what they were keeping at home and 'to make sure they had a sufficient supply'. As for the observer bias the case agreement with other studies might suggest that this is not a major source of error.

The other source of participant bias lies in the response to questionnaire where it could be argued that the patients of the intervention group have built up a better rapport with the investigator, thus responding in a way that could tend to 'please' her rather than be an honest response. This is particularly true of the *SIMS* questionnaire where the intervention group were questioned specifically about the quality of medication information by the same person who had also provided the counselling. There is little that could have been done to minimize this other than involving an independent assessor to conduct the questionnaire during the home visit. The results must therefore be taken with caution and viewed as a pilot for future work.

The same argument may not be applied to the NHP as the investigator gave no direct information or offered counselling regarding the various aspects of health issues covered by the instrument. The investigator built up a similar rapport between the two groups other than discussion of the medication. Thus, a quite similar amount of time was spent in the assessment process and conversations unrelated to medication. Therefore, there is little reason to support that the intervention group would try to present a different health status than the control group in order to give a different impression to the interviewer.

6.7 Ethical Issues

The most problematic area of ethical concerns was that of non-intervention in the control group. This arose when a MRP was identified during the domiciliary visits within the control group where some interventions were necessary. In all such cases, the problems were referred to the clinical pharmacist based at the hospital. In most cases, she judged the problems were non urgent and no action was taken until the second home visit. In a few cases, action did need to be taken. There was also the situation were on questioning there were obvious and potentially important gaps in knowledge were observed *e.g.,* concerning drug regimen and they had to be corrected by the researcher. These factors may partially explain the shift in improvement regarding knowledge and level of MRPs in the control group, though to a lesser degree than the intervention group.

The other important area is in comparing the intervention to the usual care *i.e.,* control group patients were deprived of the service. This was discussed with senior hospital staff before commencing the study. It was concluded that whilst it was desirable to offer a full medication discharge service to all elderly patients, there were not currently the resources to do so although the results of the study may encourage further funding. Therefore, this was a service provided over and above that given in most hospital in the UK. A further related point is that the clinical staff were not fully aware of the nature of the study. This was done to minimize the potential variable of an increased intervention in the control group by hospital staff. It could be argued that is unethical as it is possible all patients may benefit simply from this increased awareness. In addition, it is also possible that any increased activity by the hospital would fall after few weeks as the novelty of the researcher activities declined. This has not been well studied and it was decided that removing the variable would yield more reliable data with very little impact on patient's care. However, a general outline of the project was presented to all the relevant medical and healthcare professionals in the investigated wards *e.g.,* consultants, senior staff nurses and senior pharmacist during one of the regular monthly wards meetings informing them about the nature of the study. These meeting did not normally involve the basic grade pharmacists or the regular staff nurses.

6.8 The Implication of the Study for the Health Service

The importance of the medicine management approach to patient discharge is well described in the Department of Health Document "discharge from hospital: pathway, process and practice" (2003). An appendix in this document described the importance of medicines management at two levels; the process within the hospital whereby an accurate medication history is obtained and the patient prepared for discharge and the interface issues concerning communication of information. It describes the approach to the discharge process in relation to medicines as well as the common problems encountered such as confusion concerning communication of information to the GP. The report describes how better use could be made of pharmacists and pharmacy technicians which facilitates the process. Examples are given regarding counselling of patients before discharge and pharmacists generated information letters to GPs and community pharmacists similar to the strategies involved in this study. They also describe how community pharmacists can follow-up recently discharged patients and visit them to resolve potential problems and although they imply that this is an established service in some part of the UK, there is little evidence that this is the case.

Therefore, the DoH has recently recognized the areas covered in the present study which are of direct relevance to the provision of an NHS service concerning discharge medication. One point not considered by the DoH document was the possibility of hospital-based liaison worker visiting patients in their own homes, as was examined in this study. When considering the implication of the findings of this study for service, a number of points need to be addressed:

- What are the benefits of the pre-discharge counselling process?
- What advantages can be identified concerning the extra information sent to GPs and community pharmacists?
- Was there any advantage in a hospital based liaison worker visiting two weeks post hospital discharge?
- What level of pharmacy practitioner would deliver the service?

These points can be considered from the various outcome measures.

There were measurable benefits from discharge counselling in terms of patient knowledge and compliance. However, at two weeks post hospital discharge compliance rates were reasonably high in the absence of counselling but the numbers falling between the 85%-115% range in the control group compared to intervention would seem to make counselling session worthwhile. Knowledge was also high in a number of areas seen in the absence of counselling although it improved overall as a result of the provided service. Perhaps more attention could be given to those areas of knowledge that were very poor, such as side effects. It is also likely that MRPs were reduced as a result of this counselling as related to areas such patient's understanding and discontinuing old stock of medication they were taking at home. The latter point was seen in the fewer incidences of inappropriate drugs and doses in the counselled group at two weeks post hospital discharge.

The extra information sent to GP and pharmacist may have also had important benefits two weeks post hospital discharge in terms of interface issues. Although it is true that a number of problems resulted from poor information on admission and the hospital being unaware of the regular home medication, it is likely that the advice to take no medication which had not been prescribed on discharge unless confirmed specifically by the GP helped the situation seen by the much lower incidence of this class of problem in the intervention group. However, it does highlight the need to improve medication history taking on admission. It can not be identified from this study that letters to the community pharmacists added any specific advantage, but their activities were not specifically recorded and further studies would be recommended with this aspect.

It is less clear whether a hospital-based liaison worker offered any specific advantage to the service. Further home counselling seemed to maintain compliance levels high for a further four weeks, but the longer term maintenance was not assessed. May be it is worth carrying further investigation for longer period of time to study the effect on the long-term compliance. It is likely that over a year this would fall back to that of the control group. Similarly, no particular advantage in improving patients' knowledge was observed during the second assessment although again maintained at the high level for a further month. In terms of MRPs, it is quite difficult to draw firm conclusion regarding the role of the hospital-based liaison worker. Certainly, in many categories there seems to be a trend for further reducing

the incidences of MRPs by a domiciliary visits and this may also be a result of the quite high number of interventions where the GPs needed to be contacted in the intervention group. However, there is also a general decline in the incidence of some MRPs in the control group, though not as great as that in the intervention. One factor may be that after the two week period, the discharge letters eventually did get through to the GP system and thus, certain issues are resolved. Evidence for this can be seen in the same levels of interface issues for control and intervention groups at six weeks. In addition, some of the interventions made by the researcher at two weeks did not relate to specific discharge issues but other problems identified since discharge. It is debatable whether a community pharmacist or other workers would have identified similar problems as opposed to a specific liaison worker. Overall, it does appear that a home visit has some benefits in terms of MRPs but many interface issues are resolved without such visits.

There was about half the numbers of drug related re-admissions in the intervention group *i.e.*, three in the intervention compared to six for the control. If this was true reduction, it could provide strong economic justification for the system. This can be confirmed by a much larger study.

The investigator was trained to the level of proficiency of a junior pharmacist/ senior technician. Some problems were identified that needed the specific intervention of a more senior clinical pharmacist, although most of the activities could be accomplished without any direct involvement of such a person. It was however, very useful to the researcher to have access to a senior colleague regarding certain problems identified during the domiciliary visit. The important message is that the service can be delivered relatively economically with junior staff.

In summary, the implications for the service are:

1. A 15 minute counselling session should be incorporated into the discharge plan for elderly patients and this can be accomplished by junior staff. It should be conducted to a set pro-forma as in this study.

2. Letters describing the intended discharge medication and those medications discontinued should be sent to GP and nominated community pharmacist. This can also be performed by junior pharmacy staff.

3. A visit should be made to elderly patients at two weeks post hospital discharge but there is no need to generally counsel the patients unless there are specific issues regarding knowledge/compliance and likely this should reduce the time spent during each visit.

4. The main focus of the domiciliary visits should be in identifying the MRPs, particularly as they relate to the use of older stocks of medication and other issues that have arisen recently since discharge.

5. The study could identify no particular advantage of a liaison pharmacist worker in the process of domiciliary post discharge as many of the interventions did not require a specific contact with the hospital. The domiciliary visits could be equally performed by community-based pharmacist.

6. It would be recommended that trusts concentrate resources on effective discharge counselling and improved communication to GPs/CPs rather than an outreach liaison worker. This study is the first to identify and classify the full range of MRPs reduced by such a system at two weeks post discharge.

6.9 Limitations and Implications of the Study for Future Research

The issues of the limitations of the study and implications for future research have been discussed through this chapter. For clarity these are summarized as bullet points below with a cross references to the relevant sections:

1. The study was restricted to one hospital and one health authority; therefore it cannot be assumed that the results are representative of other hospitals and other health authorities (Section 6.2.1.7).

2. Because of the time limit of this study, each patient was reviewed over a period of six weeks from the day of hospital discharge but the National Service Framework for Older People recommended that all patients aged 75 and over should be reviewed annually and those on four and more medications should receive a twice yearly review (Section 6.4.6).

3. The limitations of tablet counts in measuring compliance have been previously described. It was less convenient to use this technique alone in this study and should involve more than one type of assessment to support the results obtained by the tablet counts. Patient's self-reporting can be a useful tool in assessing patient's non-adherence which is one type of the MRPs (Section 6.4.2.3).

4. The system used to assess knowledge was not fully validated, but this is also true of most similar studies (Section 6.4.3.3).

5. In this study, the same person intervened and assessed the patients' outcomes, which made the study non-blinded (Section 6.4.3.3). The only step that could be taken to minimize the suspected bias was to use structured questionnaires. Regarding the identified MRPs, two raters assessed the type and severity of these problems to minimize the bias.

6. Calculating the percent of the patients' knowledge and compliance for the total number of medication prescribed/patient was not the most accurate way of comparison due to

the great variation between the numbers of medication each patient was prescribed (Section 6.4.3.3).

7. It was difficult to ascertain whether the questionnaires measured satisfaction with the programme per se or alternatively with the key role played by the investigator in the delivery and the management of the programme. This limitation is common to many patient satisfaction questionnaires and the researcher had no alternative but to administer the questionnaire herself (Section 6.4.5).

8. Due to the average medication number of 8 on discharge, it was difficult to calculate the *SIMS* score for each prescribed medicine as meant to be and a single administration to express the average satisfaction with the information of all of the medication patients were taking was performed, which is less accurate than calculating it for each item (Section 6.4.5).

9. The process of identification of the MRPs depended mainly on an observational experience and non-structured patient interview which is more subjective and may be a source of bias. A more structured interview should be designed to guarantee the consistency of the process of identifying the MRPs (section 6.4.6).

10. Due to limited resources, the second rater was the main supervisor of this study which may be a potential source of bias. The only approach being adopted to overcome this potential bias was offering blind data to the second investigator (the second rater was not aware which patient was control and which was intervention). Variation in the degree of agreement between the two raters may be attributed to different sources of information available to both raters. It would be more useful if the domiciliary visits were audio-recorded. Also, it would be useful if a third party shared in the process of rating or using a professional panel (Section 6.4.8).

In general terms, the study has confirmed the usefulness of pre-discharge counselling as found by others. Future research will need to assess the added benefit of medication history taking on admission and then assess the full range of MRPs as in the present study. Further

work is also needed to identify the potential benefits of community-based pharmacist or technician visiting at two weeks post discharge after a patient has had a complete pre-discharge counselling service, again assessed in terms of full range of MRPs.

There are some interesting findings regarding the outcomes of the NHP and this need to be confirmed in a large study. It would be useful to examine other quality of life instruments in this context. The calculated compliance represents an absolute figure; it would be also interesting to examine the effect of patients' beliefs on their compliance and its effect on the medication-taking behaviour. Much work is needed to standardize methods of assessing medication knowledge and also classify types of interface issues.

Summary

- The pharmacist medication counselling programme provided a significant increase in patient adherence to and knowledge about the prescribed medication in comparison to the patients of the control group. Patient's knowledge was significantly improved during the first home visit which emphasizes the importance of counselling prior to hospital discharge.

- To improve patient compliance and knowledge of their medication, verbal instruction in addition to supplementary written information may prove to be helpful.

- Although patients showed a fairly high level of compliance, medication review and patient education in the community can still improve a patient's compliance with medication in the short term.

- Patient education prior to and post hospital discharge has little impact on a patient's quality of life.

- Counselled patients showed higher satisfaction with the information provided prior to hospital discharge than the control group.

- Patients of the control group showed higher numbers of MRPs compared to the intervention group patients during both the first and the second assessments.

- Side-effects were reported to be high in the intervention group as the process of counselling itself may raise patients' awareness of side-effects.

- Insufficient awareness of health and the disease was the most common group of problems that patients of the control group suffered from during both the first and the second visits.

- The two main intervention categories performed to resolve the identified problems were "patient medication counselling" and "prescriber informed only". Both categories were related mainly to service-related problems rather than clinical-related problems. The first intervention dealt with patient knowledge and the second dealt with interface issues.

- Communication between the investigator and the GPs managed to resolve various interface issues from reissuing old medications to discontinuation of new medications prescribed in the hospital to duplication of medications.

- A moderate degree of agreement between two different raters proved that medicine and service-related classification is a valid and reliable system to be used as a MRPs classification system.

Conclusion

1. A compliance level >85% was found for the patients educated prior to hospital discharge in comparison to 75% for patients who did not receive any structured counselling. This supports the Alternative Hypothesis which states: "Patients who undertake structured discharge scheme have ***better compliance*** to medication two and six weeks post hospital discharge compared to the control group".

2. The absence of any significant changes in the patient's quality of life criteria although they received hospital discharge counselling, supports the Null Hypothesis which states: "Patients who undertake structured discharge scheme show ***no difference in their quality of life*** post hospital discharge compared to the control group".

3. A 20% increment in patients' knowledge total score for the patients who received counselling sessions prior to hospital discharge, in comparison to only a 5% increment in those patients who did not receive any structured education, supports the Alternative Hypothesis which states: "Patients who receive intensive education session prior to and two weeks after hospital discharge show ***improvement in their medication knowledge*** about their medication post hospital discharge in comparison to the control patients who receive no further education".

4. Patient knowledge improved after counselling at discharge, but little improvement observed after the first home visit. Therefore, counselling post discharge to improve medication knowledge may have little benefit.

5. *SIMS* average score of 8 for the patients who received structured education in comparison with an average score of 1 for non-counselled patients supports the Alternative Hypothesis which states: "Structured planned discharge schemes have ***a positive effect on patient's satisfaction*** for the intervention group compared to the control group two weeks post hospital discharge".

6. Patients who received the structured discharge scheme and medication review showed ***significant differences regarding the numbers and the types of the medication-related problems and the intervention*** they experienced compared to the control group two and six weeks after hospital discharge.

7. On discharge from the study site, there were relatively few instances of many clinically-related problems such as interactions, contraindications and inappropriate therapy. This may represent good attention to pharmaceutical care pre discharge.

8. There was a significant reduction of potential MRPs in the intervention group which could be attributed to a poor knowledge of health and disease. This may be a reflection of the counselling process.

9. There appears to be a slight increase in reporting ADRs in the intervention group. This may be due to improvement in patient knowledge regarding such problem.

10. About 25% of the patients in the control group had identifiable interface issues two weeks post hospital discharge, but only 12% of the intervention had such problem. However, at the second visit about 10% had such problem in either group. This may indicate that such problems are generally resolved post discharge but may be prevented by good communication and counselling pre discharge.

11. For the intervention group, the prescriber was contacted concerning MRPs for 34% of the patients after the first home visit and about 10% at the second home visit.

12. Structured discharge counselling with a single follow-up visit is to be recommended to resolve interface, compliance and patient education issues.

13. The study produced an effective tool for use in counselling patients both pre and post discharge.

14. The study produced a validated novel system for identifying and quantifying a range of medication-related problems related to the discharge processes.

15. Closer communication is required between the hospital and the community health care professionals to ensure the continuation of the correct treatment.

16. Patient's follow-up after discharge into the community and liaising with General Practitioners has the benefit of reducing any discrepancies between the medications prescribed in the hospital and those prescribed in the community.

17. The community pharmacist failed to provide pharmaceutical care service post hospital discharge.

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APPENDICES

Appendix I

Mental Status Questionnaire

No: Name: Date:

	Score
Name	0/1
Age	0/1
Time (to nearest hour)	0/1
Name & Address for 5 minutes recall	
This should be repeated by the patient to ensure it has been heard correctly	
Mrs. John Brown	0/1/2
42 West Street	0/1/2
Gateshead	0/1
Day of the Week	0/1
Day (correct day of the month)	0/1
Month	0/1
Year	0/1
Place: Type of Place (i.e. Hospital)	0/1
Name of hospital	0/1
Name of Ward	0/1
Name of town	0/1
Recognition of Two Persons (doctor, Nurse, ect.)	0/1/2
Date of Birth (day & month sufficient)	0/1
Place of Birth (town)	0/1
School Attended	0/1
Former Occupation	0/1
Name of Wife, Sib or Next of kin	0/1
Date of World War I (year Sufficient)	0/1
Date of World War II (year Sufficient)	0/1
Name of Present Prime Minster	0/1
Months of Years Backward	0/1/2
Count 1-20	0/1/2
Count 20-1	0/1/2

Appendix II

Patient Counselling Check List

No: **Ward:** **Bed:**

Name:

DOB: / /19 **DOA:** / /200

Date: / **/200**

Gender:☐ Male☐ Female

Address:

Postal Code: ☐☐☐☐ ☐☐☐

Tel No:

Name of GP:

Address of GP:

Phone Number:

Address of Community Pharmacy:

Phone number:

Date of Planned Discharge: / /200

Time:

Date of Writing TTO: / /200

Time of writing TTO:

Discharged Patient is:

☐ Medication self-administering

☐ Medication Supervised

Destination:

☐ Home ☐ Nursing Home

☐Residential Home ☐Community centre

☐ Others

Date of Dispensing TTO: / /200

Diagnosis/Drug Sensitivity/Allergy

Drugs on Admission:

a. b. c. d.

e. f. g. h.

TTO:

See Attached copy of TTO

COUNSELLING:

Date of Counselling: / /200 Time counselling started: Time counselling finished:

Information Given:

	Drug 1	Drug 2	Drug 3	Drug 4	Drug 5	Drug 6	Drug 7	Drug 8	Drug 9	Drug 10
Name:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Why:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
New Medicines										
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Strength:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Dose & Frequency										
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Time (how should it be timed with meals & other medications):										
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Instructions & Precautions:										
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Common Side Effects & What to do if they occur:										
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Duration of courses										
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Forgotten Dose☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Further Supply: ☐ Disposing: ☐ Written Information: ☐

The Same Pharmacy: ☐ Regular Visits to GP: ☐ Stop Old Medication: ☐

Give Patient Opportunity to Ask(Write What the patient will ask)

Patient Recall:

Repeat Purpose of each Medication:

☐ Correct ☐ Incorrect ☐ Some

Repeat Dosage Instruction:

☐ Correct ☐ Incorrect ☐ Some

Check Ability to the Tablets or Capsule out of the Blisters & to Open Containers & to use inhalers:

Appendix III

Nottingham Health Profile

No. Name: Date: Visit No.

Listed below are some problems people may have daily. Look down the list & put a tick in the box under YES for any problem you have at the moment. Tick the box under NO for any problem you don't have. Please answer every question. If you are not sure whether to answer YES or NO, tick whichever answer you think is more true at the moment:

I'm tired all at home:	☐ Yes	☐ No
I Have pain at night	☐ Yes	☐ No
Things are getting me down	☐ Yes	☐ No
I have unbearable pain	☐ Yes	☐ No
I take tablets to help me sleep	☐ Yes	☐ No
I've forgotten what is like to enjoy myself	☐ Yes	☐ No
I'm feeling on edge	☐ Yes	☐ No
I find it painful to change position	☐ Yes	☐ No
I feel lonely	☐ Yes	☐ No
I can only walk about indoors	☐ Yes	☐ No
I find it hard to bend	☐ Yes	☐ No
Everything is an effort	☐ Yes	☐ No
I'm waking up in the early hours of the morning	☐ Yes	☐ No
I'm unable to walk at all	☐ Yes	☐ No
I'm finding it hard to make contact with people	☐ Yes	☐ No

Remember if you are not sure whether to answer "Yes" or "No" to a problem, tick whichever answer You think more true to the moment.

The days seem to drag	☐ Yes	☐ No
I have troubles getting up & downstairs/steps	☐ Yes	☐ No
I find it hard to reach for things	☐ Yes	☐ No
I'm in pain when I walk	☐ Yes	☐ No
I lose my temper easily these days	☐ Yes	☐ No
I feel there is nobody I'm close to	☐ Yes	☐ No
I lie awake for most of the night	☐ Yes	☐ No
I feel as if I'm losing control	☐ Yes	☐ No
I'm in pain when I'm standing	☐ Yes	☐ No
I find it hard to dress myself	☐ Yes	☐ No
I soon run of energy	☐ Yes	☐ No
I find it hard to stand for long (e.g. at the kitchen sink, waiting for the bus)	☐ Yes	☐ No

I'm in constant pain	☐ Yes	☐ No
It takes me a long time to get to sleep	☐ Yes	☐ No
I feel I'm a burden to people	☐ Yes	☐ No
Worry is keeping me awake at night	☐ Yes	☐ No
I feel that life is not worth living	☐ Yes	☐ No
I sleep badly at night	☐ Yes	☐ No
I'm finding it hard to get on the people	☐ Yes	☐ No
I need help to walk about outside (e.g. walking aid or someone to support me)	☐ Yes	☐ No
I'm in pain when going up & down stairs/steps	☐ Yes	☐ No
I wakeup feeling depressed	☐ Yes	☐ No
I'm in pain when I'm sitting	☐ Yes	☐ No

Scoring System- Nottingham Health Profile

Code	Question	Weighting	Code	Question	Weighting
EN 1	1	39.26	EM 4	20	9.76
P 1	2	12.91	SO 3	21	20.13
EM 1	3	10.47	SL 3	22	27.26
P 2	4	19.74	EM 6	23	13.99
SL 1	5	22.37	P 5	24	8.96
EM 2	6	9.31	PM 6	25	12.61
EM 3	7	7.22	EN 3	26	24.00
P 3	8	9.99	PM 7	27	11.20
SO 1	9	20.01	P 6	28	20.86
PM 1	10	11.54	SL 4	29	16.10
PM 2	11	10.57	SO 4	30	22.53
EN 2	12	36.80	EM 7	31	13.95
SL 2	13	12.57	EM 8	32	16.21
PM 3	14	21.30	SL 5	33	21.70
SO 3	15	19.36	SO 5	34	15.97
EM 4	16	7.08	PM 8	35	12.64
PM 4	17	10.79	P 7	36	5.83
PM 5	18	9.30	EM 9	37	12.01
P 4	19	11.22	P 8	38	10.49

Appendix IV

Patient Knowledge

No: Name: Date: Time:

Were you taking any pills/tablets before coming to /after leaving the hospital?
☐ Yes ☐ No

Do you remember how many types of pills you were taking?
☐ Yes ☐ No

Do you know the names of the medicines you are taking?
☐ Yes ☐ No ☐Some
Drug 1:..... Drug 2:.....
Drug 3:..... Drug 4:.....
Drug 5:..... Drug 6:.....
Drug 7:..... Drug 8:.....
Drug 9:..... Drug 10:.....

Do you know the reasons for taking the medicines?
☐ Yes ☐ No ☐Some
Drug 1:..... Drug 2:.....
Drug 3:..... Drug 4:.....
Drug 5:..... Drug 6:.....
Drug 7:..... Drug 8:.....
Drug 9:..... Drug 10:.....

Do you know what the medicines look like?
☐ Yes ☐ No ☐ Some
Drug 1:..... Drug 2:.....
Drug 3:..... Drug 4:.....
Drug 5:..... Drug 6:.....
Drug 7:..... Drug 8:.....
Drug 9:..... Drug 10:.....

Have any of your medicines been altered since admission to the ward/discharge?
☐ Yes ☐ No ☐ I don't know

Have you been prescribed any new medication since hospital admission/ discharge?
☐ Yes ☐ No ☐ I don't know

Do you know the Strengths of the medicines?
☐ Yes ☐ No ☐ Some
Drug 1:..... Drug 2:.....
Drug 3:..... Drug 4:.....
Drug 5:..... Drug 6:.....
Drug 7:..... Drug 8:.....
Drug 9:..... Drug 10:.....

Do you take your tablets at special time each day:

☐ Yes ☐ No

Do you know the quantities of the medicines taken with each dose?

☐ Yes ☐ No ☐ Some

Drug 1:..... Drug 2:.....
Drug 3:..... Drug 4:.....
Drug 5:..... Drug 6:.....
Drug 7:..... Drug 8:.....
Drug 9:..... Drug 10:.....

Do you know the times of administration?

☐ Yes ☐ No ☐ Some

Drug 1:..... Drug 2:.....
Drug 3:..... Drug 4:.....
Drug 5:..... Drug 6:.....
Drug 7:..... Drug 8:.....
Drug 9:..... Drug 10:.....

Do you know any specific instructions regarding the medicines?

☐ Yes ☐ No ☐ Some

Drug 1:..... Drug 2:.....
Drug 3:..... Drug 4:.....
Drug 5:..... Drug 6:.....
Drug 7:..... Drug 8:.....
Drug 9:..... Drug 10:.....

Do you know any medication shouldn't be taken in conjunction with yours?

☐ Yes ☐ No ☐ Some

Do you know the most common or most serious side effects?

☐ Yes ☐ No ☐ Some

Drug 1:..... Drug 2:.....
Drug 3:..... Drug 4:.....
Drug 5:..... Drug 6:.....
Drug 7:..... Drug 8:.....
Drug 9:..... Drug 10:.....

Do you know what to do if side-effects occur?

☐ Yes ☐ No

Do you know what to do if you forget to take drugs?

☐ Yes ☐ No ☐ Some

Drug 1:..... Drug 2:.....
Drug 3:..... Drug 4:.....
Drug 5:..... Drug 6:.....
Drug 7:..... Drug 8:.....
Drug 9:..... Drug 10:.....

Can you read this label?

☐ Yes ☐ No

Can you open this bottle?
☐ Yes ☐ No

Can you count out 3 pills?
☐ Yes ☐ No

Do you know that your pills will only last 14/30/90 days and that you must see your own doctor?
☐ Yes ☐ No

Do you know how to obtain a new supply of medicines?
☐ Yes ☐ No

Do you get your own prescription from:
☐ Chemist ☐ GP

Do you see your GP regularly?
☐ Yes ☐ No

Do you usually visit more than one pharmacy?
☐ Yes ☐ No ☐ Sometimes

Can you get to your chemist?
☐ Yes ☐ No

Does any one help you take your medicines?
☐ Yes ☐ No ☐ Sometimes
If yes or sometimes, what does this help involve?

How do you remember to take your medications?

What do you do with medication you no longer use?

Appendix V

Satisfaction with Information about Medicines Scale (SIMS)

We would like to ask you about ***the information you have received about your medicines.*** Please rate the information you have received about each of the following aspects of your medicines. If you use more than one medicine, please give your overall feeling about information you have received ***about all your medicines.***

Rate	*Too much*	*About right*	*Too Little*	*None received*	*None needed*
1. What your medicine is called					
2. What your medicine is for					
3. What it does					
4. How it works					
5. How long it will take to act					
6. How you can tell if it is working					
7. How long you will need to be on your medicine					
8. How to use your medicine					
9. How to get a further supply					
10. Whether the medicine has any unwanted effects (side effects)					
11. What are the risks of you getting side effects					
12. What you should do if you experience unwanted side effects					
13. Whether I can drink alcohol whilst taking this medicine					
14. Whether the medicine interferes with other medicines					
15. Whether the medication will make me feel drowsy					
16. Whether the medication will affect my sex life					
17. What you should do if you forget to take a dose					

Other information (please specify below)

Action and Usage sub-scale: items 1-9

Potential Problems of Medication sub-scale: items 10-17

Appendix VI

PCNE Classification scheme for Drug-Related Problems V4

The Problems
Each problem should be coded separately, but there may be more causes or interventions to one problem.

Primary Domain	Code	Problem
1. Adverse reactions Patient suffers from an adverse drug event	**P1.1**	Side effect suffered (non-allergic)
	P1.2	Side effect suffered (allergic)
	P1.3	Toxic effects suffered
2. Drug choice problem Patient gets or is going to get a wrong (or no drug) drug for his/her disease and/or condition	**P2.1**	Inappropriate drug (not most appropriate for indication)
	P2.2	Inappropriate drug form (not most appropriate for indication)
	P2.3	Inappropriate duplication of therapeutic group or active ingredient
	P2.4	Contra-indication for drug (incl. Pregnancy/breast feeding)
	P2.5	No clear indication for drug use
	P2.6	No drug prescribed but clear indication
3. Dosing problem Patient gets more or less than the amount of drug he/she requires	**P3.1**	Drug dose too low or dosage regime not frequent enough
	P3.2	Drug dose too high or dosage regime too frequent
	P3.3	Duration of treatment too short
	P3.4	Duration of treatment too long
4. Drug use problem Wrong or no drug taken/administered	**P4.1**	Drug not taken/administered at all
	P4.2	Wrong drug taken/administered
5. Interactions There is a manifest or potential drug-drug or drug-food interaction	**P5.1**	Potential interaction
	P5.2	Manifest interaction
6. Others	**P6.1**	Patient dissatisfied with therapy despite taking drug(s) correctly
	P6.2	Insufficient awareness of health and diseases (possibly leading to future problems)
	P6.3	Unclear complaints. Further clarification necessary
	P6.4	Therapy failure (reason unknown)

Appendix VII

PCNE Classification Scheme for Drug Related Problems V4

The Causes

N.B. One problem can have more causes

Primary Domain	Code	Cause
1. Drug/Dose selection The cause of the DRP is related to the selection of the drug and/or dosage schedule	**C1.1**	Inappropriate drug selection
	C1.2	Inappropriate dosage selection
	C1.3	More cost-effective drug available
	C1.4	Pharmacokinetic problems, incl. ageing/deterioration in organ function and interactions
	C1.5	Synergistic/preventive drug required and not given
	C1.6	Deterioration/improvement of disease state
	C1.7	New symptom or indication revealed/presented
	C1.8	Manifest side effect, no other cause
2. Drug use process The cause of the DRP can be related to the way the patient uses the drug, in spite of proper dosage instructions (on the label)	**C2.1**	Inappropriate timing of administration and/or dosing intervals
	C2.2	Drug underused/ under-administered
	C2.3	Drug overused/ over-administered
	C2.4	Therapeutic drug monitoring required
	C2.5	Drug abused (unregulated overuse)
	C2.6	Patient unable to use drug/form as directed
3. Information The cause of the DRP can be related to a lack or misinterpretation of information	**C3.1**	Instructions for use/taking not known
	C3.2	Patient unaware of reason for drug treatment
	C3.3	Patient has difficulties reading/understanding Patient Information Form/Leaflet
	C3.4	Patient unable to understand local language
	C3.5	Lack of communication between healthcare professionals
4. Patient/Psychological The cause of the DRP can be related to the personality of the patient.	**C4.1**	Patient forgets to use/take drug
	C4.2	Patient has concerns with drugs
	C4.3	Patent suspects side-effect
	C4.4	Patient unwilling to carry financial costs
	C4.5	Patient unwilling to bother physician
	C4.6	Patient unwilling to change drugs
	C4.7	Patient unwilling to adapt life-style
	C4.8	Burden of therapy
	C4.9	Treatment not in line with health beliefs
5. Logistics The cause of the DRP can be related to the logistics of the prescribing or dispensing mechanism	**C5.1**	Prescribed drug not available
	C5.2	Prescribing error (only in case of slip of the pen)
	C5.3	Dispensing error (wrong drug or dose dispensed)
6. Others	**C6.1**	Other reason; specify
	C6.2	No obvious reason

Appendix VIII

PCNE Classification scheme for Drug-Related Problems V4

The Interventions

N.B. One problem can lead to more interventions

Primary Domain	Code	Intervention
No intervention	**I0.0**	No Intervention
1. At prescriber level	**I1.1**	Prescriber informed only
	I1.2	Prescriber asked for information
	I1.3	Intervention proposed, **approved** by Prescriber
	I1.4	Intervention proposed, **not approved** by Prescriber
	I1.5	Intervention proposed, outcome unknown
2. At patient/carer level	**I2.1**	Patient (medication) counselling
	I2.2	Written information provided only
	I2.3	Patient referred to prescriber
	I2.4	Spoken to family member/caregiver
3. At drug level	**I3.1**	Drug changed to ….
	I3.2	Dosage changed to ….
	I3.3	Formulation changed to …..
4. Other intervention or activity	**I4.1**	Other intervention (specify)
	I4.2	Side effect reported to authorities

Appendix IX

Case Study

Patient No.1
Sex: Female
Age: 82

Medications on Discharge	Diagnosis on Discharge
Bisoprolol 20mg OD	Hypertension
Amlodipine 5mg OD	
Bendrofluazide 2.5mg OD	
Simvastatin 10mg ON	Hypercholesteroleamia
Paracetamol 500mg QDS	Severe Osteoarthritis Spine
DHC 30mg PRN MAX TDS	
Lansoprazole 30mg OM	Minor Reflux Oesophagitis
Gaviscon 10mls PRN Max TDS	Hiatus Hernia

Problems on Discharge
Patient is sensitive to NSAIDs, causing her GI bleeding.

Findings during home visits
First Home visit (two weeks after discharge)

Repeated Medication			Compliance%
Paracetamol 500mg	ii	QDS	PRN
Tramadol 50mg	I	ON	50
Amlodipine 5mg		OD	100
Bendrofluazide 2.5mg		OD	100
Bisoprolol 10mg		OD	100
Lansoprazole 30mg		OD	100
Simvastatin 10mg		ON	100
Gaviscon		PRN	PRN

- Pain was not controlled: Gp prescribed Tramadol together with the DHC.
- Feeling sick with the Tramadol and the DHC: she stopped both of them.
- I found the patient was taking DHC regularly instead of when required and it caused nausea and vomiting, she contacted her GP and replaced the DHC with Tramadol but also caused nausea and vomiting, so she stopped it as well.
- She is using Senna (OTC) I OD.
- She does not feel and GIT problems: GP stopped Gaviscon.

Drug Related Problems
DHC and Tramadol: Nausea and Vomiting (……)
She was suffering from constipation maybe as a side effect of the Tramadol and DHC (……..).

II. Second Home Visit (six weeks after discharge)

Repeated Medication		Compliance%
Paracetamol 500mg	ii QDS	Prn
Tramadol 500mg	I ON	100
Amlodipine 5mg	OD	100
Bendrofluazide 2.5mg	OD	100
Bisoprolol 10mg	OD	100
Lansoprazole 30mg	OD	100
Simvastatin 10mg	ON	100
Gaviscon	PRN	PRN

- She got a new tense machine: she reduced the doses of the pain killers to half
- She doesn't feel any sickness with the Tramadol any more.

Drug Related Problems:

-

Quantifying the DRPs:

	Medicine-Related	Service-related	Total
1st Visit			
2nd Visit			

Outcomes:

- ☐ Problems not controlled.
- ☐ Problems controlled.
- ☐ Some problems were controlled.
- ☐ Further Intervention.
- ☐ Readmission to the Hospital Before the Second Home Visit.
- ☐ Died

Endpoint:

- Nausea and vomiting disappeared after regular use of Tramadol.
- Pain was much controlled.
- No hospital readmission during the first six weeks

Rate of Hospital Readmission during Six Months:

None

Nottingham Health Profile

	Pain	Energy	Emotion	Sleep	Social Isolation	Physical Mobility
Before Discharge	75.3	60.80	00	00	00	87.34
2 weeks	69.77	00	00	00	00	87.34
6 weeks	31.86	24	00	00	00	87.34

APPENDICES

Patient's Knowledge:

	Name	Reason	Shape	Strength	Dose	Time	Instructions	Side effects
Before Discharge	71.4	57.1	71.4	42.9	14.3	71.4	00	00
2 weeks	100	100	100	00	100	100	14.3	00
6weeks	100	66.7	100	16.7	100	100	50	00

Transportation time to the nearest half an hour:
First Home Visit: 1 hrs.
Second Home Visit: 1 hrs.

Length of the home visit to the nearest Half an Hour:
First Home Visit: 2 hrs.
Second Home Visit: 1.5 hrs.

No of GP visits
One visit one week after discharge from the hospital.

APPENDICES

Patient No.: 8

Sex: Male
Age: 80

Medications On Discharge		**Diagnosis on Discharge**
Aspirin 75mg	OD	TIA
Warfarin	as directed	
Salbutamol Inhaler 100	ii PRN	SOB
Tamsulosin 400mcg	OD	Prostatic Hyperplasia
Frusemide 40mg	ii OD	Hypertension
Lisinopril 2.5mg	OD	
Digoxin 125mcg	OD	AF

Problems on Discharge:
Patient is allergic to Penicillin.

Findings during the home visits:
I. First Home Visit (After Two Weeks):

Repeated Medications		**Compliance**
Aspirin 75mg	OD	--
Warfarin	as directed	--
Tamsulosin 400mcg	OD	--
Co-amilofruse 5/40	ii OD	--
Lisinopril 2.5mg	OD	--
Digoxin 125mcg	OD	--

- Patient was using an old stock of his medication, so measuring compliance was very difficult in addition that he kept part of his medication at his daughter house where he goes there every weekend.
- Patient was using Co-amilofruse instead of frusemide and he thought that both are the same.
- Patient stopped using the salbutamol inhaler.
- Patient is very good complier, he was making his own calendar which he marked every time he took him medication.

Drug Related Problems:
- (Frumil) rather than the new one (Frusemide) (……).
- Clinical interaction between Frumil, Lisinopril and Digoxin (……).

Intervention:
- ☐ Non
- ☐ Contact the GP
- ☐ Contact the Hospital
- ☐ Contact the Pharmacist
- ☐ Advise the Patient
- ☐ Others

II. Second Home Visit (After Six Weeks):

Repeated Medications	Compliance
Aspirin EC 75mg OD	--
Warfarin as directed	--
Tamsulosin 400mcg OD	--
Co-amilofruse 5/40 I OD	--
Lisinopril 2.5mg OD	--
Digoxin 125mcg OD	--
Aspirin dispersible 75 mg OD	--

➢ Compliance was difficult to be calculated because patient used to spend some times at his daughter place and he was keeping a stock of the medication there as well.

Drug-Related Problems:

➢ Repeating old medication (Frumil) rather than the new one (Frusemide) (……).
➢ Clinical interaction between Frumil, Lisinopril and Digoxin (……).

Quantifying the DRPs:

	Medicine-related	Service-related	Total
1st Visit			
2nd Visit			

Outcomes:

- ❑ Problems not controlled.
- ❑ Problems controlled.
- ❑ Some problems were controlled.
- ❑ Further Intervention.
- ❑ Readmission to the Hospital Before the Second Home Visit.
- ❑ Died

Endpoint:

- ❑ Blood pressure well controlled.
- ❑ INR within the range.

Rate of Hospital Re-admission During Six Month:

-

Nottingham Health Profile

	Pain	Energy	Emotion	Sleep	Social Isolation	Physical Mobility
Before Discharge	00	60.8	7.22	61.53	00	65.45
2 weeks	00	00	00	12.57	00	10.79
6 weeks	00	00	00	12.57	00	23.84

APPENDICES

Patient's Knowledge:

	Name	Reason	Shape	Strength	Dose	Time	Instructions	Side effects
Before Discharge	60	60	00	00	00	00	00	00
2 weeks	66.6	50	83.3	00	100	100	00	00
6weeks	83.33	100	100	00	100	100	16.66	00

Transportation time:

First Home Visit: 45 minutes.
Second Home Visit: 45 minutes.

Length of the home visit to the nearest Half an Hour:

First Home Visit: 45 minutes.
Second Home Visit: 30 minutes.

No of GP visits:

-

APPENDICES

Appendix X

Table 46 Comparison between the scores obtained by the senior pharmacist to the scores scored by the investigator for each item marked in the checklist

Pt	No. of Medicine	Name[1] P/I[2]	Why[3] P/I	Strength P/I	Dose & frequency P/I	New[4] P/I	Time[5] P/I	Instructions P/I	SE[6] P/I	Duration[7] P/I	Forgotten dose[8] P/I	Supply[9] P/I	Written information[10] P/I	GP visit[11] P/I	Old medication[12] P/I
1	3	3/3	3/3	0/0	3/2	0/0	0/2	0/1	1/1	0/0	0/0	0/0	0/0	0/0	0/0
2	4	4/4	4/4	1/1	4/4	1/3	2/2	0/0	2/2	0/0	0/0	1/1	0/0	1/1	0/1
3	3	3/3	3/3	0/0	1/2	1/1	1/1	0/0	0/0	½	0/0	1/1	0/0	1/1	1/1
4	6	6/6	6/6	4/4	5/6	0/0	0/0	¾	0/0	0/0	0/0	0/0	0/0	0/0	0/0
5	10	10/10	10/10	0/0	10/10	0/0	7/6	2/3	1/2	0/0	0/0	0/0	0/0	0/0	0/0
6	7	7/7	7/7	0/0	7/7	1/1	7/7	¾	2/2	0/0	0/0	0/0	1/1	0/0	0/0
7	7	7/7	7/7	1/1	7/7	2/2	5/5	0/0	2/2	0/0	0/1	1/1	0/0	0/0	1/1
8	5	5/5	6/6	0/0	6/6	4/4	6/5	2/2	2/2	2/2	4/6	1/1	1/1	0/0	1/1
9	5	5/5	4/5	2/3	5/5	3/3	2/2	3/3	1/1	0/0	0/0	1/1	1/1	1/1	0/1
10	5	5/5	5/5	4/5	5/5	2/2	4/4	2/2	0/0	0/0	1/1	1/1	0/0	0/0	1/1
Total	55	55/55	55/56	12/14	53/54	14/16	34/34	15/19	11/12	4/4	7/7	6/6	3/3	3/3	5/6

[1] Name: giving the name of the medicine
[2] P/I: Senior Pharmacist/ Investigator
[3] Why: Describing the purpose of the medicine
[4] New: Informing the patient with any new medicine
[5] Time: Relating the doses with the regular events and the time of the meals.
[6] SE: Side effects
[7] Duration: Informing the patient with the duration of the therapy
[8] Forgotten dose: Informing the patient what to do if he or she forget to take a dose
[9] Supply: Telling the patient how to get further supply of the medication
[10] Written information: Providing the patient with written information
[11] GP visit: Remind the patient with the importance of contacting the GP before the medicine supply runs out.
[12] Old medication: Describe to the patients what to do with the old medications they have

%	100	100	98.2	85.71	98.14	87.5	100	78.9	91.7	87.5	85.71	100	100	100	83.33	

Appendix XI

St. Thomas' Hospital Ethical Committee Approval

Guy's and St Thomas' Hospital NHS
NHS Trust

ST THOMAS' HOSPITAL RESEARCH ETHICS COMMITTEE
Medical Committee Office
Block 5, South Wing

Chairman - Dr G du Mont
Administrator - Ms S Hirsch

St Thomas' Hospital
Lambeth Palace Road
London SE1 7EH

Tel: 020 7928 9292

Ext 2097 Fax 0171 922 8163
Stella.hirsch@gstt.sthames.nhs.uk

6 December 2001

Nirmeen Mohammed
Ph.D Student
Department of Pharmacy, KCL
150 Stamford Street,
Waterloo
SE1 8WA

Dear Ms Mohammed

EC01/188 **Hospital discharge planning and interface liaison for elderly care patients** *Nirmeen Mohammed, Larry Goodyear, Russell Greene, Louise Gallard*

Thank you for addressing the queries raised by the Research Ethics Committee at its meeting on 30 October 2001. This is satisfactory and I am happy for the study to commence. Approval extends to the Guy's site.

Please note the following conditions to the approval:

- The project number and the principal investigator must be clearly stated on the consent form (if applicable). If approval is given to named investigators only, these names must also be stated on the form.
- In the case of research on patients, a copy of the consent form (if applicable) must be placed in the patient's medical records, together with a note of the date of commencement of his/her participation in the research. A label must appear on the outside cover of the records when the patient is participating in the research.
- Any amendments to the protocol must be notified to the committee for approval.
- Approval is for the length of time specified in your application. If you require an extension, a letter from the principal investigator to the Chairman, is required to extend the research.
- The committee should be notified of any serious adverse events (please apply for standard SAE report form), or if the study is terminated prematurely
- The investigators must adhere to the published Guidelines of the Committee and provide the Chairman with annual progress reports and an end of study report. The research should start within 12 months of the date of approval.

This project carries a reference number, noted above, which must be quoted in any future correspondence.

The St Thomas' Hospital LREC is compliant with the ICH GCP requirements.

Yours sincerely

Dr G du Mont
Chairman
Research Ethics Committee

Encl.

Appendix XII

St Thomas' Hospital Research Ethics Committee

CONSENT FORM FOR PARTICIPATION IN RESEARCH PROJECTS & CLINICAL TRIALS

Title of Project: Hospital Discharge Planning and Liaison

Principal Investigator: N. Mohammed Sawat **Other Investigator/s:** L.Goodyer, L. Coughlan **enrolling patients**:	**Ethics Committee** **Code No**:

Outline explanation:

I would like to ask you to take part in a study that we are conducting. The purpose of the study is to see how patients take their medication & if the can benefit from any advice that is given to them before hospital discharge. We would also like to see whether it is of any advantage to pass information about you to a community pharmacist.

If you decide to take part, then just before you go home I will ask you some questions about your medications and general health. You may be given some extra information about your medication. In addition, you may also be asked to elect a community pharmacist from whom you would like to obtain any medicines over the next two months. The community pharmacist will be sent a list of the medicines that you are going home with together with any other information that might help him in advising you on your medication.

I will visit you at home after two weeks and six weeks to ask you some questions concerning your medication and your general health.

I (name)

_____

of (address)

_____

hereby consent to take part in the above investigation, the nature and purpose of which have been explained to me. Any questions I wished to ask have been answered to my satisfaction. I understand that I may withdraw from the investigation at any stage without necessarily giving a reason for doing so and that this will in no way affect the care I receive as a patient

SIGNED (Volunteer) _____ **Date** _____

(Doctor)_____ **Date** _____

(Witness, where appropriate) _____ **Date** _____

3 copies required:- one for researcher, one for patient/volunteer, one for patient's notes

Appendix XIII

Protocol for Predischarge Counselling

Aim: To encourage the understanding of and compliance with the prescribed drug regime.

(i) Pharmacist should introduce himself/herself and ensure that the patient is not distracted.

(ii) Explain that the patient is to take home medication prescribed by the doctor.

(iii) Give advice with as much clarity as possible, using simple language.

(iv) Explain he importance of the medication to the patient's well being.

(v) Show each tablet or capsule to patient, indicating the name and giving an explanation of use.

(vi) Go through the label with the patient, ensuring directions are understood.

(vii) Distinguish between regular and "prn" drugs.

(viii) IF the patient does not appear to understand the instructions, they should be reiterated gently but persistently, introducing a few new facts each time.

(ix) Ensure that the patient can open the container (including sachets).

(x) Ask if the patient usually has any "problem" with his/her tablets.

(xi) Explain that only the hospital medicines should be used and not any that may already be at home.

(xii) Avoid technical terms.

(xiii) Always give the most important points first.

(xiv) Repeat the important points and be specific in the advice.

Appendix XIV

Information About your Medicine

This chart shows the medications you've been discharged from the hospital with, this chart will be collected after two weeks from the discharging date.

After your visit to your GP, some of your medications maybe subjected to some changes.

This chart shows you when to take each of your medicines.

At each mealtime, look down the column to see which medicines you need to take with or just after the meal. Do the same about half an hour before bedtime.

Some Important Things to Remember about Using Medications:

- **Never take another person's medication.**
- **Never stop taking medication without call doctor first.**
- **Never change the dose of medication unless the doctor tells you.**
- **Never take old or outdated medication.**
- **Never mix medications with alcoholic beverages.**
- **Never transfer pills from original container to another one.**
- **Never take medication in the dark.**

APPENDICES

No:
Name:
Date: / /200
Discharge Date: / /200

Name of Medication & the Form	Strength	Amount to be Taken	Reason for Taking Medicine	Time to Take Your Medicine				Common Side Effects	Special Instructions
				Morning	Lunch	Dinner	Bed Time		

Appendix XVa

Letter to General Practitioner

Pharmacy Department
Pharmacy Practice Group
King's College London
150 Stamford St.

Pharmacy Department
Elderly Care
St. Thomas' Hospital

Dear Dr :

The Pharmacy department at King's College London, in conjunction with the Pharmacy department in St. Thomas' Hospital & the Care of the Elderly department, is currently running a study concerning patient discharge. The primary of the study is to investigate the potential benefits of a more structured discharge programme concerning patient medication.

I have identified one of your patients, Mrs/Mr.....as a candidate for the study, & have planned for a home visit in the near future.

As part of this study I shall be making two home visits to Mr./ Mrs. ..... Who has agreed to take part. The propose of these visits is to assess medication usage and general quality of life.

In addition, Mr./ Mrs.....has elected a community pharmacist to whom details of their discharge medication is sent. They will be collecting all medication prescribed by you from this pharmacist over at least the next two months.

If you feel that that such home visit may not be appropriate for this patient, or you would like further information about the project, then please call or write to Miss N. Mohammed Safwat in the Pharmacy Department.

Sincerely, yours,

N. Mohammed Safwat
Ph.D. Student (Pharmacy Practice)
King's College London
150 Stamford Street, SE1 8NN
E-mail: Nirmeen.mohammed_safwat@kcl.ac.uk

Patient's Name:
Address:
Date of Birth:
Date of Admission: **Date of Discharge:**
Name of Consultant:
Reasons of Hospital Admission

.....
.....

Diagnosis during Hospital Stay

.....
.....
.....
.....

Old Medication Stopped on Discharge	**Reason**
.....	.....
.....	.....
.....	.....

New Medication started	**Reason**
.....	.....
.....	.....
.....	.....
.....	.....

Other Comments

.....
.....
.....
.....

Appendix XVb

Letter to General Practitioner

Pharmacy Department
Pharmacy Practice Group
King's College London
150 Stamford St.

Pharmacy Department
Elderly Care
St. Thomas' Hospital

Dear Dr :

The Pharmacy department at King's College London, in conjunction with the Pharmacy department in St. Thomas' Hospital & the Care of the Elderly department, is currently running a study concerning patient discharge. The primary of the study is to investigate the potential benefits of a more structured discharge programme concerning patient medication.

I have identified one of your patients, Mrs/Mr.....as a candidate for the study, & have planned for a home visit in the near future.

As part of this study I shall be making two home visits to Mr./ Mrs. ..... Who has agreed to take part. The propose of these visits is to assess medication usage and general quality of life.

If you feel that that such home visit may not be appropriate for this patient, or you would like further information about the project, then please call or write to Miss N. Mohammed Safwat in the Pharmacy Department.

Sincerely, yours,

N. Mohammed Safwat
Ph.D. Student (Pharmacy Practice)
King's College London
150 Stamford Street, SE1 8NN
E-mail: Nirmeen.mohammed_safwat@kcl.ac.uk

Appendix XVI

Letter to Community Pharmacist

Pharmacy Department
Pharmacy Practice Group
King's College London
150 Stamford St.

Pharmacy Department
Elderly Care
St. Thomas' Hospital

Dear :

The Pharmacy department at King's College London, in conjunction with the Pharmacy department in St. Thomas' Hospital & the Care of the Elderly department, is currently running a study concerning patient discharge. The primary of the study is to investigate the potential benefits of a more structured discharge programme concerning patient medication & the transfer of information between hospital & community pharmacy.

I have identified Mrs/Mr.....as a candidate for the study and I have planned for a home visit in the near future. Mrs/ Mr.....has elected your pharmacy to where details of his/her discharge medication will be sent. Mrs/ Mr.....will collect all medication prescribed by the GP from this pharmacy over the next two months.

A copy of the patient's medication, which will go home with, will be sent to your pharmacy together with any relevant discharge information concerning the patient medical case.

As part of this study I shall be making two home visits to Mr./ Mrs.....who has agreed to take part. Propose of these visits is to assess medication usage and general quality of life.

If you would like further information about the project, then please call or write to Miss N. Mohammed Safwat in the Pharmacy Department.
Sincerely, yours,

N. Mohammed Safwat
Ph.D. Student (Pharmacy Practice)
Department of Pharmacy,
King's College London
150 Stamford Street, SE1 8NN
E-mail: Nirmeen.mohammed_safwat@kcl.ac.uk

Patient's Name:
Address:
Date of Birth:
Date of Admission: **Date of Discharge:**
Name of Consultant:
Name of GP: **Phone Number:**
Reasons of Hospital Admission

.....

Diagnosis during Hospital Stay

.....
.....
.....
.....

Old Medication Stopped on Discharge	**Reason**
.....	.....
.....	.....
.....	.....

New Medication started	**Reason**
.....	.....
.....	.....
.....	.....

Other Comments

.....
.....
.....
.....

Appendix XVII

CHECKLIST OF HOME VISIT
TWO/SIX WEEKS AFTER HOSPITSL DISCHARGE

No: Name: Date: Group:

	Medication & regimen	No. of tablets now	No. of tablet dispensed	Date of dispensing	% compliance
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

Medication related problems:

☐ ADRs

☐ Interaction

☐ Therapeutic Failure

☐ In appropriate Prescribing

☐Physical Difficulties

☐ Compliance

☐ Knowledge

☐ Interface Issues

☐Dosing Problems

☐ Others

Details

Checklist:

☐ Knowledge

☐ Satisfaction

☐ MRPs

☐ Counselling

General Comments

Appendix XVIII

Table 6.4 Frequencies and Percents of the Most Commonly Diagnosed Medical Problems

Disease	Number of Patients (%)*		
	Control	Intervention	Both
Cardiovascular Problems			
Hypertension	30(49.2)	38(62.3)	68(55.7)
Angina & Myocardial Infarction	27(44.3)	24(39.4)	51(41.9)
Aterial Fibrillation	8(13.1)	14(23)	22(18)
Heart Failure	6(9.8)	8(13.1)	14(11.5)
Stroke &CVA	15(24.6)	14(23)	29(23.8)
Other cardiac diseases	28(46)	32(52.5)	60(49.2)
Gastrointestinal Problems			
Ulcers	4(6.6)	3(4.9)	7(5.7)
Hernia	4(6.6)	4(6.6)	8(6.6)
Others	19(31.1)	25(41)	44(36.1)
Respiratory Problems			
COPD &Asthma	22(36.1)	20(32.8)	42(34.4)
Other respiratory diseases	4(6.6)	5(8.2)	9(7.4)
Infectious Problems			
UTI	9(14.8)	6(9.8)	15(12.3)
Chest Infection	18(29.5)	16(26.2)	34(27.9)
Other Infectious Diseases	7(11.5)	4(6.6)	11(9)
Musculoskeletal Problems			
RA &OA	12(19.7)	16(26.2)	28(23)
Others	12(19.7)	5(8.2)	17(13.9)
Central Nervous Problems			
Depression	4(6.6)	5(8.2)	9(7.4)
Other CNS Diseases	6(9.8)	4(6.6)	10(8.2)
Endocrinological Problems			
Diabetes	16(26.2)	9(14.8)	25(20.5)
Thyroid Diseases	7(11.5)	4(6.6)	11(9)
Fall	9(14.8)	10(16.4)	19(15.6)
Anemia	10(16.4)	6(9.8)	16(13.1)
Renal Problems	10(16.4)	9(14.8)	19(15.6)
Hepatic Problems	2(3.3)	1(1.6)	3(2.5)
Eye Problems	3(4.9)	8(13.1)	11(9)
Miscellaneous	41(67.2)	35(57.4)	76(62.3)
Total No. of Recruited Patients	61	61	122

* Column Percent

Appendix XIX

BNF Categories and Frequencies of Medication Prescribed on Discharge

Category	Drug or Class	Number of Medication (%)		
		Control	Intervention	Total
Cardiovascular	Diuretics	35 (7.3)	35 (8.1)	70 (7.7)
	Nitrates	16 (3.3)	17 (4)	33 (3.6)
	ACEIs	21 (4.4)	23 (5.3)	44 (4.8)
	Calcium Channel Blockers	15 (3.1)	19 (4.4)	34 (3.7)
	Beta-blockers	10 (2.1)	11 (2.6)	21 (2.3)
	Cardiac Glycoside	7 (1.5)	11 (2.6)	18 (2)
	Anticoagulants &Antiplatelets	41 (8.6)	47 (10.9)	88 (9.7)
	Lipid Regulating Drugs	17 (3.6)	19 (4.4)	36 (4)
	Others	14 (2.9)	14 (3.3)	28 (3.1)
Total		**176 (36.7)**	**196 (45.6)**	**372 (40.9)**
Central Nervous	Non-Opioid Analgesics	24 (5)	26 (6)	50 (5.5)
	Opioid Analgesics	9 (1.9)	7 (1.6)	16 (1.8)
	Antidepressants	9 (1.9)	6 (1.4)	15 (1.7)
	Others	14 (2.9)	8 (1.9)	22 (2.4)
Total		**56 (11.7)**	**47 (10.9)**	**103 (11.3)**
Gastrointestinal	Laxatives	26 (5.4)	19 (4.4)	45 (5)
	PPIs	30 (6.3)	21 (4.9)	51 (5.6)
	Others	2 (0.4)	9 (2.1)	11 (1.25)
Total		**58 (12.1)**	**49 (11.4%)**	**107 (11.8)**
Respiratory	Beta Agonists	29 (6.1)	22 (5.1)	51 (5.6)
	Steroids Preparations	27 (5.6)	23 (5.3)	60 (7)
	Others	16 (3.3)	16 (3.8)	44 (1.9)
Total		**72 (15)**	**61 (14.2)**	**133 (14.6)**
Musculoskeletal	NSAIDs	8 (1.7)	5 (1.2)	13 (1.4)
	Others	2 (0.4)	7 (1.6)	9 (1)
Total		**10 (2.1)**	**12 (2.8)**	**22 (2.4)**
Topical Preparation	Eye/Ears/Nose/Skin	11 (2.3)	14 (3.3)	25 (2.8)
Total		**11 (2.3)**	**14 (3.3)**	**25 (2.8)**
Endocrine	Oral Hypoglycaemics	14 (2.9)	4 (0.9)	18 (2)
	Insulin	4 (0.8)	2 (0.5)	6 (0.7)
	Thyroid Preparations	4 (0.8)	5 (1.2)	9 (1)
	Others	13 (2.7)	6 (1.4)	18 (2)
Total		**35 (7.3)**	**17 (4)**	**51 (5.6)**
Obstetrics, Gynaecology	Obstetrics & Gynaecology	3 (0.6)	1 (0.2)	4 (0.4)
& Urinary Tract	Urinary Tract	3 (0.6)	3 (0.7)	6 (0.7)
Total		**6 (1.3)**	**4 (0.9)**	**10 (1.1)**
Miscellaneous	Anti Aneamic	8 (1.7)	9 (2.1)	17 (1.9)
	Vitamins &Minerals	26 (5.4)	9 (2.1)	35 (3.9)
	Antibacterial& Antifungal	21 (4.4)	12 (2.8)	33 (3.6)
Total		**479**	**430**	**909**

Appendix XX

Patient Medication Knowledge Scores Assessed before Hospital Discharge

Question	Score Mean % (SD)	
	Control	**Intervention**
Number of patients	59	60
1. Name	46.8 (32.8)	43.4 (31.5)
2. Purpose	63.2 (28.4)	66 (26.5)
3. Shape	65.2(29.9)	69.9(28.2)
4. Dose	64.9(32.1)	69.5(29.2)
5. Time	64.7(32.0)	67.3(29.1)
6. Strength	15.9(21.8)	21.9(30.5)
7. Special Instructions	16.5(22.7)	14.4(20.1)
8. Side Effects	4.4(11.4)	5.8(12.0)

Appendix XXI

Nottingham Health Profile Administered to both the Control and the Intervention Groups before Hospital Discharge

Area	Mean Sore (SD)	
	Control	**Intervention**
No. of Patients	58	58
Pain	28.7 (27.3)	22.2 (27.5)
Energy	47.9 (37.5)	35.5 (39.0)
Emotion	25.6 (23)	18.8 (21.9)
Sleep	41.3 (31)	32.0 (33.4)
Social Isolation	19.8 (20.8)	14.6 (20.0)
Physical Mobility	47.2 (22.9)	35.7 (26)

Appendix XXII

Numbers of Patients Suffering from Different MRPs (According to PCNE)

Category	Number of Patients (%)*			
	1st Visit		2nd Visit	
	Control	Intervention	Control	Intervention
Side effect	13(26.5)	17(34)	10(25.7)	14(35)
Inappropriate drug or form (not most	3(6.1)	3(6)	3(7.7)	2(5)
Inappropriate duplication of therapeutic	1(2.0)	2(4)	2(5.1)	1(2.5)
Contra-indication for drug	4(8.2)	2(4)	1(2.6)	2(5)
No clear indication for drug use	2(4.1)	0	3(7.7)	0
No drug prescribed but clear indication	7(14.3)	3(6)	2(5.1)	1 (2.5)
Drug dose too low or regimen not frequent	10(20.4)	10(20)	10(25.6)	8(20)
Drug dose too high or dosage regimen too	6(12.2)	3(6)	6(15.4)	2(5)
Drug not taken/administered at all	16(32.7)	11(22)	8(20.5)	9(22.5)
Wrong drug taken/administered	10(20.4)	6(12)	9(23.1)	5(12.5)
Potential interaction	2(4.1)	3(6)	4(10.2)	2(5)
Patient dissatisfied despite taking drugs	7(14.3)	9(18)	7(17.9)	4(10)
Insufficient awareness of health and disease	20(40.8)	14(28)	18(46.2)	4(10)
Unclear complaints, clarification necessary	7(14.3)	5(10)	7(17.9)	4(10)
Therapy failure for unknown reason	3(6.1)	2(4)	4(10.2)	2(5)
Number of Patients	**49**	**50**	**39**	**40**

*Column percent was calculated by dividing the number of patients suffered from individual problem by the total number of patients in each study group (control or intervention) X 100.

Appendix XXIII

Numbers of Patients of Both the Control and the Intervention Groups Who Suffered from One or More MRPs

Category	Number of Patients (%)*			
	1st Visit		2nd Visit	
	Control	**Intervention**	**Control**	**Intervention**
Minor	22 (44.9)	25 (50)	21 (53.8)	13 (32.5)
Moderate	25 (51)	25 (50)	21 (53.8)	11 (27.5)
Sever	14 (28.6)	11 (22)	10 (25.6)	9 (22.5)
Total	**61**	**61**	**52**	**33**
No. of Patient Monitored	**49**	**50**	**39**	**40**

*Column percent calculated by dividing the numbers of the problems identified in each problem category in each study group by the total numbers of problems of the same study group during each visit X 100%

Appendix XXIV

Numbers of Patients of Both the Control and the Intervention Groups Who Suffered from One or More Different Service-Related Problems

Category	Number of Patients (%)*			
	1st Visit		2nd Visit	
	Control	Intervention	Control	Intervention
Polypharmacy	0 (0)	6 (12)	2 (5.1)	1 (2.5)
Interface Issues	13 (24.5)	6 (12)	5 (12.8)	4 (10)
Patient Knowledge	24 (49)	23 (46)	20 (51.3)	8 (20)
Physical Difficulty	7 (14.3)	7 (14)	6 (15.4)	3 (7.5)
Label Problems	3 (6.1)	3 (6)	5 (12.8)	2 (5)
Compliance & Memory	23 (46.9)	16 (32)	18 (46.2)	13 (32.5)
Storage Problems	6 (12.2)	3 (6)	6 (15.4)	1 (2.5)
No. of Patient	**49**	**50**	**39**	**40**

*Column percent calculated by dividing the numbers of the problems identified in each problem category in each study group by the total numbers of problems of the same study group during each visit X 100%

Appendix XXVI

Number of the MRPs during the First Home Visit as Rated by Different Investigators

Category	Total Number of Problems 1st visit							
	Control				Intervention			
	LG	NMS	Kappa	Strength of	LG	NMS	Kappa	Strength
Minor	26	29	0.7	Good	27	32	0.54	Moderate
Moderate	45	36	0.5	Moderate	39	31	0.28	Fair
Severe	20	20	0.4	Fair	6	11	0.5	Moderate
Average Kappa Score			**0.53**	**Moderate**			**0.44**	**Moderate**
				0.48 Moderate				
Total No. of Problems	**91**	**85**			**12**	**74**		

Number of the MRPs during the Second Home Visit as Rated by Different Investigators

Category	Total Number of Problems 2nd visit							
	Control				Intervention			
	LG	NMS	Kappa	Strength of Agreement	LG	NMS	Kappa	Strength of Agreement
Minor	19	22	0.47	Moderate	19	16	0.6	Moderate
Moderate	26	30	0.43	Moderate	15	14	0.65	Good
Sever	16	10	0.42	Moderate	9	9	0.86	Very Good
Average Kappa Score			**0.44**	**Moderate**			**0.7**	**Good**
				0.57 Moderate				
Total No. of Problems	**61**	**62**			**43**	**39**		

Number of the Service-Related Problems during the First Home Visit as Rated by Different Investigators

Category	Total Number of Problems 1st visit							
	Control				Intervention			
	LG	NMS	Kappa	Strength	LG	NMS	Kappa	Strength
Polypharmacy	0	0	1	Very Good	4	6	0.78	Good
Interface Issues	15	13	0.7	Good	9	6	0.78	Good
Patient Knowledge	21	24	0.43	Moderate	7	23	0.46	Moderate
Physical Difficulty	7	7	1	Very Good	7	7	0.91	Very Good
Label Problems	4	3	0.85	Very Good	3	3	1	Very Good
Compliance & Memory	26	23	0.76	Good	16	16	0.73	Good
Storage Problems	4	6	0.78	Good	4	3	0.85	Very Good
Average Kappa Score			**0.79**	**Good**			**0.78**	**Good**
				0.79 Good				
Total No. of Patients	**73**	**76**			**51**	**64**		

Number of the Service-Related Problems during the Second Home Visit as Rated by Different Investigators

Category	Total Number of Problems 2nd visit							
	Control				Intervention			
	LG	NMS	Kapp	Strength	LG	NMS	Kapp	Strength
Polypharmacy	1	2	0.51	Moderate	1	1	1	Very
Interface Issues	6	5	0.64	Good	5	4	0.63	Good
Patient Knowledge	10	20	0.46	Moderate	9	8	0.86	Very
Physical Difficulty	6	6	1	Very Good	3	3	1	Very
Label Problems	8	5	0.8	Good	4	2	0.64	Good
Compliance and Memory	26	18	0.8	Good	16	13	0.76	Good
Storage Problems	7	6	0.79	Good	1	1	1	Very
Average Kappa Score			**0.71**	**Good**			**0.84**	**Very**
				0.77 Good				
Total No. of Patients	**64**	**62**			**39**	**32**		

Appendix XXVI
Interventions Done at the Prescriber Level for the Intervention Group

First Home Visit

Patient 5
GP was sent another copy of the TTO and the changes happened to the patient's medication

Patient 7
GP was contacted to confirm the changes happened to the patient's medication, as patient kept both new and old medication and was not sure which one to use.

Patient 14
Investigator contacted the consultant to query about the reason of stopping the Naproxen and the possibilities of put the patient on Naproxen back as it was the only medicine controlling patient's pain. Consultant explained the reason for stopping it and said it was stopped as a cautious step because the patient has recent pacemaker operation and he can take Naproxen again.

GP was contacted to prescribe Frusemide as 20mg OD rather than half tablet of the 40mg OD.

Patient 16
GP was contacted to confirm the changes happened to the patient medication, as old medications were re-prescribed.

Patient had difficulties swallowing Paracetamol table, so GP was contacted to prescribe Paracetamol caplet or capsule instead.

Patient 20
Patient suffered from hematurea, GP was informed and he advised to stop the Warfarin till the INR being checked again.

Patient suffered from UTI and when the GP was contacted he prescribed Trimethoprim.

Patient suffered from Nausea since she started the Digoxin, when GP contacted he advised to stop the Digoxin.

Patient 21
GP decided suddenly to stop Rohypnol which the patient was on it for more than 10 years. GP was contacted to re-prescribing it again and trying to reduce the dose rather than stopping it suddenly.

Patient suffered from Nausea because of the Co-proxamol. GP was contacted to change it and Paracetamol was prescribed instead.

Patient 23
Consultant was contacted regarding the Irbesartan which the patient stopped by mistake. The consultant confirmed that the patient should restart it again which she did.

Patient 32
Patient was prescribed 5mg Bendrofluazide instead for 2.5mg. GP was contact and he said it was a mistake and the 2.5mg was prescribed again.

Patient 33
GP was contacted to inform him regarding patient's poor memory and the effect of this on patient's compliance.

Patient 40
Consultant was contacted regarding the Oedema patients suffered and he recommended prescribing a diuretic.

GP was contacted to prescribe a suitable diuretic for the Oedema. Bendrofluazide 2.5mg PRN was prescribed.

Patient 44
Patient left the hospital with Frusemide 80mg OD but the one dispensed from the Pharmacy had label of 40mg OD. GP was contacted to confirm if this was intentional or just a mistake. GP confirmed it was a mistake and patient was told to take two tablets.

Patient 47
Stroke patient suffered from incontinence. Stroke Unit was contacted and an outpatient appointment was arranged.

GP was contacted regarding patient's poor memory and the effect of that on her adherence.

Patient 48
Quinine Sulphate found among patients medication although it was not prescribed during the hospital stay and was not included in the drug history list. GP was contact to query about this, and he confirmed that the patient was suffering from night cramps and was on Quinine Sulphate before the admission.

GP was contacted to prescribe Paracetamol as Caplet or Capsule instead of Tablet which patient had difficulties in Swallowing

Patient 57
Patient was dispensed 2mg Lorazepam instead of 0.5mg. GP was contacted to query about the discrepancy. GP confirmed it was a mistake, and the 0.5mg was prescribed again.

Patient 63
GP was contacted to confirm that Frumil (which was contribution factor for hospital admission because of fall) was stopped, and to convince the patient to stop using it, as the patient insisted on continue taking it as long her GP didn't advise her to stop it.

Patient 65
Patient was contacted regarding the newly prescribed medicines during the hospital stay and to arrange medication delivery to the housebound patient.

Patient 83
GP was contacted to attract her attention to the importance of monitoring Theophylline level which was newly prescribed to the patient. An appointment was arranged for the patient.

Second Home Visit

Patient 53
GP was contacted to start the patient on Nebuliser (as patient requested).

Patient 83
GP was contacted to arrange medication delivery to the patient or prescribe medication enough for three months rather than one month.

Patient 102
GP was contacted to query about the reason behind not re-prescribing Ranitidine and GP confirmed it was a mistake.

Patient 119
Simvastatin was prescribed by the GP as 20mg BD rather than 40mg OD (which was prescribed by the hospital). GP confirmed it meant to be 20mg OD as 40mg was too much for her and she felt tired on the 40mg.

Appendix XXVII

Different Interface Problems Identified in Patients of Both Groups during Both Home Visits

First Home Visit

Control Group Patients

Patient 2

Patient was prescribed Fosamax and Adcal during his hospital stay but this was not repeated to him post hospital discharge.

Patient 8

Frumil was stopped during the hospital stay and Frusemide was prescribed instead but this wasn't applied in the community and the patient was still on Frumil.

Patient 11

Patient had history of night cramps and was on Quinine sulphate before his hospital admission but this was not reported among the admission medication. The second problem is that the patient was using Ranitidine 300mg when required for heart burn before hospital admission and it was not on his TTO but the patient was still using it without prescription depending on an old stock he kept he kept at home.

Patient 15

Patient had history of angina and was on GTN before hospital admission but was not reported among the admission medication but the patient had already her GTN spray at home and was using it when in need.

Patient 31

Patient was on Salbutamol before admission but was not reported among admission medication but the patient repeated it from the GP.

Patient 37

Patient was diabetic and on Insulin but was not reported in her DH.

Patient 50

Patient was on GTN and Didronel before hospital admission but both were not reported among the admission medication. Patient got them during the hospital stay through the repeat prescription.

Patient 56

Patient was on Amitryptylline before hospital admission and wasn't reported among the admission medication, but it was repeated through the GP.

Patient 70
Lansoprazole was stopped during the hospital stay and was replaced with Omeprazole but stopped Lansoprazole was re-issued in the community.

Patient 94
Presence of extra medication in the Dossett Box which were not in the TTO list and couldn't find out what were they as they were not written in the card.

Patient 101
All old medication including the stopped ones were repeated during the first home visit.

Patient 103
Patient was not given a copy of the TTO, and when she went to visit her consultant during the outpatient clinic, the consultant didn't have a copy of the TTO as well and he couldn't tell what she was on and why. The second problem is lack of communication between the smoking cessation pharmacist in the hospital and the GP, so the patient didn't start her sessions till the first home visit.

Patient 111
Patient was taking Moduretic and Amitriptylline although they were stopped in the Hospital. The second problem was lack of the information taken during the admission as the patient was using Becotide Inhaler before hospital admission, but could not find anything regarding it in her Drug History. Also using Ferrous Sulphate tablets and she said it was for Anemia, but I could not find anything regarding it in her History. The third problem is Prednisolone wasn't among her medication and she did not put for repeat although it was mentioned to be repeated after the Hospital discharge.

Intervention Group
Patient 5
GP repeated the old stopped medications (Bendrofluazide and Carbamazepine) together with new medications.

Patient 16
Repeating of old prescription only without any of the new medications or the inhalers.

Patient 26
Patient was on Diclofenac for back pain before hospital admission but it was not reported in DH and she was using old stock she was keeping at home.

Patient 32
Repeating old strength of Bendrofluazide.

Patient 48
Patient had history of night cramps and was on Quinine sulphate but was not reported on admission.

Patient 81
Patient said she was on Diazepam before admission for depression but was not on her drug history.

Second Home Visit
Control Group

Patient 2
Patient was prescribed Fosamax and Adcal during his hospital stay but this was not repeated to him post hospital discharge.

Patient 8
Frumil was stopped during the hospital stay and Frusemide was prescribed instead but this wasn't applied in the community and the patient was still on Frumil

Patient 70
Lansoprazole was stopped during the hospital stay and was replaced with Omeprazole but stopped Lansoprazole was re-issued in the community.

Patient 94
Presence of extra medication in the Dossett Box which were not in the TTO list and couldn't find out what were they as they were not written in the card.

Patient 111
Patient was taking Moduretic and Amitriptylline although they were stopped in the Hospital. The second problem was not repeating Prednisolone although it was mentioned to be repeated after the Hospital discharge.

Intervention Group
Patient 53
Patient changed his accommodation and there was poor communication between the hospital and both the old and the new GP regarding patient's medication.

Patient 65
Adcal was prescribed in the hospital as ii OD but it was re-prescribed in the community as i BD (as before admission).

Patient 102
She was prescribed Ranitidine regularly during her hospital stay but was not repeated for her post discharge.

Patient 112
Patient said he was on Calcichew before admission but nothing was reported on her admission DH.